UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Medtronic, Inc. and Medtronic USA, Inc.,

Plaintiffs,

v.

Edwards Lifesciences Corp., Edwards Lifesciences, LLC, and Edwards Lifesciences (U.S.) Inc.,

Defendants.

Civil No. 11-1650 (JNE/JSM)
ORDER

Edwards Lifesciences Corp., Edwards Lifesciences, LLC, and Edwards Lifesciences (U.S.) Inc.,

Counterclaimants,

v.

Medtronic, Inc., Medtronic USA, Inc., and Medtronic Vascular Inc.

Counterdefendants.

Plaintiffs Medtronic, Inc. and Medtronic USA, Inc. (collectively, "Medtronic") brought this patent infringement action against Defendants Edwards Lifesciences Corp., Edwards Lifesciences, LLC, and Edwards Lifesciences (U.S.) Inc. (collectively, "Edwards"). Edwards counterclaimed, asserting patent infringement claims against Medtronic. The case is before the Court to construe disputed patent claim terms pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

I. BACKGROUND

Medtronic accuses Edwards of infringing four patents: U.S. Patent No. 7,468,073 (filed Apr. 11, 2006)) ('073 Patent), U.S. Patent No. 7,503,929 (filed Jan. 23, 2006) ('929 Patent), U.S.

Patent No. RE42,395 (filed Oct. 12, 2007) ('395 Patent), and U.S. Patent No. 6,004,330 (filed Mar. 3, 1995) ('330 Patent). Edwards accuses Medtronic of infringing three patents (the "McCarthy Patents"): U.S. Patent No. 6,749,630 (filed Aug. 28, 2001) ('630 Patent), U.S. Patent No. 8,114,155 (filed Apr. 14, 2008) ('155 Patent), and U.S. Patent No. 8,123,800 (filed Apr. 14, 2005) ('800 Patent).

The '073, '929 and '395 Patents are directed toward bioprosthetic valve systems and holders used during surgical procedures to replace diseased heart valves. The '073 Patent and the '929 Patent are related patents with the same inventors and claim priority to the same provisional application filed January 2, 2002. The '330 Patent is directed toward a device used to filter and manipulate matter within the body. In this litigation, Medtronic asserts claims 1-4 and 6-13 of the '073 Patent, claims 1-5 and 19 of the '929 Patent, claim 9 of the '395 Patent, and claims 1, 4, 7, 8, 10, 15, and 17-19 of the '330 Patent.

The three McCarthy Patents are members of the same patent family and all have the same inventors. The patents relate generally to annuloplasty, a surgical procedure used to improve the functioning of the mitral and tricuspid valves in the heart. During annuloplasty, an artificial ring is sewn onto the natural annulus of the valve to provide support to the valve. The '630 and '155 Patents relate to the annuloplasty rings; the '800 Patent relates to the template used to deliver the annuloplasty ring to the surgical site.[1] Edwards asserts claims 1, 10 and 11 of the '630 Patent, claims 1-4, 9, 11-14, 16, 19, 21-22 and 27 of the '155 Patent, and claims 1, 4-8, 10-12, 15-19, 21 and 22 of the '800 Patent.

[1] The '155 Patent is a continuation of an application that is a continuation-in-part of the '630 Patent and U.S. Patent No. 6,908,482 ('482 Patent). The '800 Patent is a divisional of the '482 Patent. The specifications of the McCarthy Patents are very similar, and at times identical.

II. DISCUSSION

The construction of patent claims "is a matter of law exclusively for the court." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). "[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). Words of a claim are generally given their ordinary and customary meaning, which is the meaning that the term would have to a person of ordinary skill in the pertinent art at the time of the invention. *Id.* at 1312-13. "[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, a court should look to the sources available to the public that show what a person of skill in the art would have understood the claim language to mean. *Id.* at 1314. "Those sources include 'the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.'" *Id.* (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

The claims provide substantial guidance as to the meaning of particular claim terms. *Id.* In some cases, the use of a term within the claim provides a firm basis for construing the term. *Id.* Other claims of the patent can be valuable sources of enlightenment as to the meaning of a claim term. *Id.* "Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Id.* In addition, differences between claims can help determine the meaning of particular claim

terms. *Id.* For example, a dependent claim that adds a particular limitation creates a presumption that the limitation is not present in the independent claim. *Id.* at 1314-15.

The claims do not stand alone, however, and "must be read in view of the specification, of which they are a part." *Id.* at 1315 (internal quotation marks omitted). The specification is "always highly relevant" to claim construction and usually is dispositive because it is "the single best guide to the meaning of a disputed term." *Id.* (internal quotation marks omitted).

In addition to the claims and specification, a court should consider the patent's prosecution history, if it is in evidence. *Id.* at 1317. The prosecution history can "inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

Finally, a court may consider extrinsic evidence, which is "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Id.* (internal quotation marks omitted). Extrinsic evidence, however, is less significant than the intrinsic record in claim construction. *Id.*

A. '073 Patent

The '073 Patent, entitled "Heart Valve System," claims a heart valve and holder, preferably for use in aortic valve repairs. A bioprosthetic heart valve typically includes a structural stent, from which commissure posts extend. The valve leaflets attach to these commissure posts. The replacement heart valves also include a sewing ring, which the surgeon sutures to the native tissue of the heart. During implantation of the replacement valve, the valve is attached to a holder that enables the surgeon to position the valve at the appropriate site and securely hold the valve in place until suturing is complete. Once the valve is sutured to the heart

tissue, the holder is separated from the valve. Prior art valve holders attached to the commissure posts of the valve, which impeded the surgeon's access to the surgical site and precluded any inward deflection of the commissure posts. The valve holder of the '073 Patent improved upon the prior art by disclosing a valve holder that attached to the body of the valve "in the valleys defined between the commissure posts," thus improving the surgeon's access and permitting the commissure posts to be inwardly deflected during implantation. '073 Patent col. 3 ll. 11-13; *see also id.* col. 1 ll. 54-57.

The parties request that the Court construe the following terms recited in the claims of the '073 Patent: "valve body," "a holder having a holder body comprising a central portion engagable with a holder handle," and "a holder having a holder body comprising a central portion coupled to a holder handle." These terms appear in several claims of the '073 Patent, but the Court need not recite all of the claims here, since the relevant portions of the various claims are nearly identical. Claim 1 recites:

> 1. A bioprosthetic heart valve system, comprising: a heart valve comprising a valve body having a plurality of commissure posts extending to a first end of the valve body, each commissure post ending in a tip portion, a stent including a peripheral edge at a second end of the valve body, and a sewing ring that is spaced from the tip portions of the commissure posts and extending along the peripheral edge defining a ring structure at the second end of the valve body; and a holder having a holder body comprising a central portion engagable with a holder handle and having a plurality of legs extending downwardly from the central portion, releasably coupled to the valve body intermediate the commissure posts.

Claim 7 recites:

> 7. A bioprosthetic heart valve system, comprising: a heart valve . . . ; and a holder having a holder body comprising a central portion coupled to a holder handle and having a plurality of legs extending downwardly from the central portion, releasably coupled to the valve body intermediate the commissure posts.

1. "Valve body"

The claim language provides that the valve body has "a plurality of commissure posts extending to a first end of the valve body . . . , a stent including a peripheral edge at a second end of the valve body, and a sewing ring that is spaced from the tip portions of the commissure posts and extending along the peripheral edge defining a ring structure at the second end of the valve body." Edwards initially proposed that the valve body also include leaflets, but has since abandoned that proposal. Edwards harbors concern, however, that Medtronic wants to include a fabric covering as part of the "valve body." The Court does not read Medtronic's proposed construction as suggesting that fabric be read into the claim language, and Medtronic did not assert at oral argument that fabric should be included. The claim language itself, which clearly provides the structure of the valve body, does not include any reference to either leaflets or fabric. With the understanding that the "valve body" as recited in the claims does not include leaflets or fabric, no further construction of this claim term is required.[2]

2. "A holder having a holder body comprising a central portion engagable with a holder handle" and "a holder having a holder body comprising a central portion coupled to a holder handle."

Edwards's proposed construction for these terms is as follows: "a holder having a holder body with a central portion that can be engaged with a holder handle to deflect the commissure posts" and "a holder having a holder body with a central portion that is connected to a holder

[2] The parties agree that the valve body includes commissure posts and a stent. Contrary to the Court's plain reading of the claim language, however, they also both agree that the valve body does *not* include a sewing ring. Since there is no dispute about the sewing ring, the Court need not address it now. The Court only notes that the parties' interpretation of the claim, excluding the sewing ring from the valve body, appears to be belied by the language and structure of the claim itself—in particular, the claim's use of commas and the word "and" before "a sewing ring."

handle to deflect the commissure posts." Medtronic contends that no construction of these claim terms is required.

The main dispute is Edwards' assertion that these claim terms require that the holder body not only be engaged or connected to the holder handle, but that the holder body also be able to deflect the commissure posts. Language concerning deflection is notably absent from the claims themselves. For support, Edwards points to language in the specification, which provides that the holder is able to inwardly deflect the stent posts. *See, e.g.*, '073 Patent, abstract; *id.* col. 1 ll. 48-67. The specification explains that the invention provides two distinct benefits: first, it provides inward deflection of the stent posts, and second, it improves a surgeon's access by attaching to the valve body in the valleys between the commissure posts. The claims expressly recite a holder that is "releasably coupled to the valve body intermediate the commissure posts." *Id.*, claim 1. But despite the specification's repeated disclosure of a holder that inwardly deflects the stent posts, conspicuously absent from the '073 Patent is any claim that actually claims such a deflection device. At first glance, this omission seems rather odd. But the '073 Patent is only one of a family of related patents—the '929 Patent also claims priority to the same provisional application. The '929 Patent, which will be discussed in greater detail below, claims a deflection device for inwardly deflecting the stent posts. Thus, it becomes clear that the claims of the '073 Patent are directed only at a holder that attaches to the valve body somewhere other than at the commissure posts, and the claims of the '929 Patent are directed at a holder that inwardly deflects the commissure posts. This construction is supported by the specification of the '073 Patent, which provides:

> It should be noted that while the preferred embodiment of the valve holder according to the present invention includes a mechanism for producing inward deflection of the commissure posts, it is believed that a holder having the general configuration illustrated, e.g. a central portion having three downwardly

> extending legs adapted to engage the valve between the commissure posts is also useful in the context of a holder which does not include a mechanism for inward deflection of the commissure posts. Such a design retains the compact overall configuration of the holder as illustrated in the present application, improving the surgeon's access as compared to a holder mounted to the tips of the commissure posts as in the [prior art]. The placement of the downwardly extending legs between the commissure posts, even without inward deflection, also still serves to provide additional protection of the leaflets of the valve against inadvertent damage . . . ."

'073 Patent col. 5 ll. 26-42.

The file history of the '073 Patent confirms that the invention is directed only at a holder that attaches to the valve body in a location between the stent posts. "[T]he present invention is directed to the provision of a holder that releasably connects between commissure posts of a stented valve . . . . The novel and unobvious holder and heart valve combination of the present invention further facilitates implantation of a heart valve of the claimed type without the holder being engaged with the commissure post tips." Hannah Decl. Ex. 22, at 8 (ECF No. 89-22). Edwards asserts that other language in the file history constitutes a clear intention by the inventor for the holder of the '073 Patent to itself be able to deflect the stent posts. "By the present amendment, independent claims 38 [claim 1 as issued], 43, 45, and 46 are amended to emphasize the valve construction of the present invention as such heart valve is provided with a specifically designed holder to facilitate implantation of the heart valve with commissure posts deflected inwardly." *Id.* "While releasably engaging the heart valve body in the valleys between commissure posts, the commissure posts can still be effectively deflected for implantation." *Id.* Contrary to Edwards' beliefs, this language does not require that the holder be able to deflect the commissure posts. Rather, these statements only emphasize the benefits of having a holder that attaches in the valleys between the posts, rather than to the tips of the commissure posts. A holder attached to the tips of the commissure posts does not allow those posts to be inwardly

deflected. In contrast, a holder attached in the valleys between the commissure posts allows for those posts to be inwardly deflected while still attached to the holder. By connecting to the valve body in this novel manner, the holder *allows for* the deflection of the commissure posts—but it need not *provide* the deflection.

The construction requested by Edwards would add limitations not found in the claims themselves. There is nothing in the intrinsic record that constitutes a clear disavowal of the broader claim scope, nor is there any other evidence that suggests it is appropriate for the Court to import a deflection limitation from the specification into the claim language. "Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language." *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004). Neither the specification nor the file history supports Edwards' proposed construction. Thus, the Court concludes that "a holder having a holder body comprising a central portion engagable with a holder handle" and "a holder having a holder body comprising a central portion coupled to a holder handle" do not require that the holder inwardly deflect the commissure posts. With that understanding, the claim language is clear and no further construction is necessary.

B. '929 Patent

The '929 Patent, titled "Prosthetic Heart Valve System," claims and discloses a prosthetic heart valve system comprising a prosthetic heart valve, a deflection device for inwardly deflecting the stent posts of the heart valve, and a holder for the heart valve. Inward deflection of the stent posts is particularly important when performing a mitral valve replacement, because during the surgical procedure, the mitral valve is implanted by placing the prosthesis "with the stent posts projecting blindly deep into the patient's left ventricle." '929 Patent col. 1 ll. 63-64.

"Due to a lack of visibility through the prosthetic valve, a surgeon can inadvertently loop sutures around the stent posts," and the "stent posts may undesirably 'snag' on chordae or trabeculae inside the left ventricular cavity." *Id.* col. 1 l. 64-col. 2 l. 2. Inward deflection is also important when performing aortic valve replacement, because during this procedure, "a surgeon is often faced with little room to maneuver," and non-deflected stent posts can interfere with the surgeon's ability to perform the maneuvers required. *Id.* col. 2 ll. 39-61. Prior art deflection devices and holders, however, were poorly suited for aortic valve replacements. *Id.* col. 2 l. 64-col. 3 l. 41. The invention of the '929 Patent sought to improve upon the prior art by disclosing a "preassembled stent post deflection device that is safe, simple in form and operation, and appropriate for any heart valve location, including the aortic valve." *Id.* col. 3 ll. 38-14.

Medtronic has asserted independent claim 1 and dependent claims 2-5 and 19 against Edwards. Claim 1 recites:

> 1. A prosthetic heart valve system comprising: a prosthetic heart valve . . . ; and a deflection device for inwardly deflecting the stent post, the deflection device including: a line interconnecting and passing through free ends of a plurality of the stent posts, a tensioning component that is movably disposed relative to free ends of the stent posts and having an end that is transitional relative to the free ends of the stent posts to a tensioning state in which the end of the tensioning component transitions the line to create tension within the line and thus to inwardly deflect at least one of the stent posts.

Claim 4 recites:

> 4. The prosthetic heart valve system of claim 3, wherein the tensioning component includes a tubular body slidably connected to the line, and further wherein the holder body defines an aperture sized to selectively retain the tubular body.

The parties request that the Court construe the following claim terms: "a deflection device for inwardly deflecting the stent posts," "a line interconnecting and passing through free ends of a plurality of the stent posts," "a tensioning component . . . to create tension within the

line and thus to inwardly deflect at least one of the stent posts," "movably disposed relative to free ends of the stent posts," "an end that is transitional relative to the free ends of the stent posts," and "tubular body slidably connected to the line."

1. "A deflection device for inwardly deflecting the stent posts"

Edwards contends that "a deflection device for inwardly deflecting the stent posts" is a means-plus-function claim under 35 U.S.C. § 112, ¶ 6 because the language is purely functional. Alternatively, if the term is not construed as a means-plus-function term, then Edwards proposes the following construction: "A single line and a connector assembly (housing or tensioning component and locking element) that bends the stent posts inward a desired amount." Medtronic argues that the claim term requires no construction and that is not a means-plus-function claim.

"[A] claim term that does not use 'means' will trigger the rebuttable presumption that [35 U.S.C.] § 112 ¶ 6 does not apply." *CCS Fitness v. Brunswick Corp.*, 288 F.3d 1359, 1369 (Fed. Cir. 2002). "The presumption that a limitation lacking the term 'means' is not subject to section 112 ¶ 6 can be overcome if it is demonstrated that 'the claim term fails to "recite sufficiently definite structure" or else recites "function without reciting sufficient structure for performing that function."'" *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1358 (Fed. Cir. 2004) (citation omitted). "[T]he presumption flowing from the absence of the term 'means' is a strong one that is not readily overcome." *Id.*

In arguing that the claim language is purely functional, Edwards focuses solely on the narrow phrase "deflection device for inwardly deflecting the stent posts." Edwards contends that this language is entirely functional, and that no structure for performing the function is recited. Edwards fails, however, to consider any of the words that immediately follow this phrase. The claim itself provides that the "deflection device" includes "a line interconnecting and passing

through free ends of a plurality of the stent posts" and "a tensioning component that is movably disposed relative to free ends of the stent posts and having an end that is transitional relative to the free ends of the stent posts." The claim itself provides sufficient structure for performing the function of inwardly deflecting the stent posts, and so Edwards has failed to overcome the presumption that section 112, ¶ 6 does not apply.

The Court also rejects Edwards' proposed alternative construction for this claim term. The claim itself recites the components of the deflection device—i.e., a line and a tensioning component. Edwards seeks to substitute "connector assembly" (consisting of a housing or tensioning component *and* locking element) for "tensioning component," a substitution which is not supported by the specification. Notably, throughout the specification of the '929 Patent, the "locking element" is treated as distinct from the "tensioning component." *See, e.g.*, '929 Patent figs.1-18B; *id.* col. 6 ll. 12-14; *id.* col. 11 ll. 47-49; *id.* col. 14 ll. 11-13; *id.* col. 15 ll.9-11; *id.* col. 17 ll. 3-5. Edwards' proposed inclusion of the word "bends" would not provide any assistance to a jury, and Edwards' requirement that the deflection be of "a desired amount" would only add more ambiguity to the claim. There is no evidence that the term "deflection device for inwardly deflecting the stent posts," when read along with the remainder of the claim language, would be unclear to a person having ordinary skill in the art. The claim language already recites the structural components of the deflection device along with the function of the deflection device. No further construction of this claim term by the Court is necessary.

2. "A line interconnecting and passing through free ends of a plurality of the stent posts"

Edwards proposes that this term, found in claim 1 of the '929 Patent, be construed as: "a single line passing through and connecting each of the free ends of the stent posts with the others." Medtronic argues that the claim term requires no construction, or alternatively, that it be

construed as "one or more lines passing through and interconnecting free ends of a plurality of the stent posts."

Edwards first notes that the patent claims and specification repeatedly refer singularly to "a line" or "the line," and thus contends that the line must be limited to "a single line." Edwards also cites to the figures of the '929 Patent, which depict a single line passing through all of the stent posts. But as Medtronic argues, "[a]s a general rule, the words 'a' or 'an' in a patent claim carry the meaning of 'one or more.'" *01 Communique Lab., Inc. v. LogMeIn, Inc.*, 687 F.3d 1292, 1297 (Fed. Cir. 2012) (internal quotation marks and citations omitted).

> The exceptions to this rule are extremely limited: a patentee must evince a clear intent to limit "a" or "an" to "one." The subsequent use of definite articles "the" or "said" in a claim to refer back to the same claim term does not change the general plural rule, but simply reinvokes that non-singular meaning. An exception to the general rule arises *only* "where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule."

Id. (internal quotation marks and citations omitted). Further, "[a] patent that describes only a single embodiment is not necessarily limited to that embodiment." *Saunders Grp., Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 1332 (Fed. Cir. 2007). "Even where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope . . . ." *Id.*; *see also Phillips*, 415 F.3d at 1323 ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments. In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." (citations omitted)); *Nazomi Commc'ns, Inc. v. ARM Holdings, PLC*, 403 F.3d 1364, 1369 (Fed. Cir. 2005) (noting that claims may embrace "different subject matter than is illustrated in the specific embodiments in

the specification"). Where the specification describes only a single embodiment, the claims will be read restrictively only if "the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp*., 299 F.3d 1313, 1327 (Fed. Cir. 2002)). Here, there has been no such demonstration.

Edwards also points to the prosecution history of a related patent in support of its construction. During the prosecution of Application No. 10/336,622, which ultimately issued as U.S. Patent No. 7,033,390,[3] the inventor stated:

> "In particular, claim 35 provides that the tensioning component is coupled to the prosthetic heart valve via a line interconnecting the free end of each of the stent posts. Similar limitations have previously been presented in at least claim 1. Nguyen Pub. No. '686 specifically teaches at paragraph 0033 that there are at least three sutures 60 extending from the three posts 26. For at least this reason, it is respectfully submitted that newly presented dependent claim 35 recites patentable subject matter of Nguyen Pub. No. '686."

Hannah Decl. Ex. 23 at 9-10 (ECF No. 89-23). Claim 35 of the '390 Patent recited: "The prosthetic heart valve system of claim 19, wherein the tensioning component is coupled to the prosthetic heart valve via a line interconnecting the free end of each of the stent posts."[4] According to Medtronic, and undisputed by Edwards, claim 35 was never allowed by the patent examiner, despite the inventor's arguments. Moreover, the language of claims 19 and 35 of the '390 Patent is different than the language at issue in the '929 Patent—the '390 Patent language related to how the tensioning component is coupled to the valve, whereas the '929 Patent is silent

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[3] The '929 Patent is a continuation of the '390 Patent.

[4] Claim 19 recited:
A prosthetic heart valve system comprising: a prosthetic heart valve . . . ; a holder including a holder body coupled to the prosthetic heart valve; and a deflection device including a tensioning component coupled to the prosthetic heart valve apart from the holder body.

regarding how the tensioning component is coupled to the valve. Thus, the prosecution history statements upon which Edwards relies were not only made during the prosecution of a different patent application, but were not critical to the issuance of any claims in any patent, and the claim language discussed during the prosecution of the '390 Patent is different than the claim language involved in the '929 Patent.

Statements made during the prosecution of a related patent may be relevant where the claim language at issue is present in both the related patent and the patent at issue. *See Saunders Grp., Inc.*, 492 F.3d at 1333 ("The fact that the prosecution history relied upon was created in connection with the parent application would be unimportant if the claim language at issue were present in both patent applications."). But "[w]hen the purported disclaimers are directed to specific claim terms that have been omitted or materially altered in subsequent applications (rather than to the invention itself), those disclaimers do not apply." *Id.*; *see also Ventana Med. Sys. v. Biogenex Labs.*,473 F.3d 1173, 1182 (Fed. Cir. 2006) ("[T]he doctrine of prosecution disclaimer generally does not apply when the claim term in the descendant patent uses different language."). Here, the statements made during the prosecution of an unissued claim in a different patent that utilized different language than the patent at issue here does not demonstrate a clear intention to limit the claim scope of the '929 Patent claims to only devices that utilize a single line. Where there are "no words of manifest exclusion or clear disavowals of [multi-line] devices," but instead "only preferred embodiments and goals of the inventions that . . . are better met by single [line] devices," then the Court will not limit the device to a single [line] component. *In re Rambus Inc.*, 694 F.3d 42, 47 (Fed. Cir. 2012).

The "line," as claimed in the '929 Patent, may be constructed of multiple lines—for example, perhaps it is desirable for two or more sutures to be twisted or braided together to form

the "line." However the line is created, it must "pass[] through free ends of a plurality of the stent posts" and be able to "inwardly deflect at least one of the stent posts." '929 Patent, claim 1. Absent any clear intent by the inventor to limit the claim scope to a single line, the Court does not construe "a line" to be "a single line."

During oral argument, the Court addressed the question of whether the "line," however that line is constructed, must go through all of the stent posts or just some of the stent posts. Edwards argued that the same line must go through all of the stent posts. Medtronic, on the other hand, asserted that while some line must to go through all of the stent posts, it need not be the same line. Thus, Medtronic seems take the position that it is sufficient if the line goes through two of the three stent posts, as long as some other line goes through the remaining stent post. The claim requires that the line pass through the free ends of "*a* plurality of the stent posts." It does not say that the line must pass through "*the* plurality of the stent posts," or in other words, all of the stent posts. Further, the claim language clearly requires that the line only must be able to deflect "at least one of the stent posts"—it is unclear how it could deflect fewer than all of the stent posts if it were required to pass through all of the stent posts, since it appears as though in that configuration, any tension applied to the line would inwardly deflect all of the posts. And while the figures of the '929 Patent depict the same line passing through all of the stent posts, it is inappropriate for the Court to import such a limitation into the claim language absent a clear demonstration that the inventor so intended. The Court therefore rejects Edwards argument. Edwards seems to suggest that if the "line" may be comprised of more than one line, and if the same line need not go through all of the stent posts, then the invention is anticipated by the prior art. If that is the case, then that may be a question for another day. But for the moment, based on the record before the Court, no construction of this claim term is required.

3. "A tensioning component . . . to create tension within the line and thus to inwardly deflect at least one of the stent posts"

Claim 1 recites "a tensioning component that is movably disposed relative to free ends of the stent posts and having an end that is transitional relative to the free ends of the stent posts to a tensioning state in which the end of the tensioning component transitions the line to create tension within the line and thus to inwardly deflect at least one of the stent posts." Edwards argues that section 112, ¶ 6 applies because the language is purely functional and that the claim does not recite sufficient structure to perform the function. Alternatively, if the Court determines that section 112, ¶ 6 does not apply, Edwards proposes the following construction: "a component that can create tension in a line where previously there was none such that at least one stent post bends inwards a desired amount." Medtronic asserts that the claim term requires no construction and that it is not a means-plus-function term. Because the claim term does not use the word "means," there is a strong rebuttable presumption that section 112, ¶ 6 does not apply. *CCS Fitness*, 288 F.3d at 1369. As previously stated, this presumption can be overcome if the claim fails to recite sufficiently definite structure, or does not recite sufficient structure for performing the stated function. *See Lighting World*, 382 F.3d at 1358.

There is no evidence that the term "tensioning component" has a generally understood structural meaning in the art. In the absence of any other claim language providing structure, this would weigh in favor of applying section 112, ¶6. *See Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206 (Fed. Cir. 1998). But other claim language that provides the necessary structure will save the claim from application of section 112, ¶ 6. *Id.* at 1213; *see also Mass. Inst. of Tech. & Elec. for Imaging, Inc. v. Abacus Software*, 462 F.3d 1344, 1354 (Fed. Cir. 2006) ("Claim language that further defines a generic term like 'mechanism' can sometimes add sufficient structure to avoid 112 ¶ 6."). Here, the claim does not merely recite "a tensioning component"

that performs the function of creating tension on the line. Rather, the claim provides that the tensioning component "is movably disposed relative to free ends of the stent posts" and has "an end that is transitional relative to the free ends of the stent posts" so that "the tensioning component transitions the line to create tension within the line and thus to inwardly deflect at least one of the stent posts." This is more than purely functional language and provides sufficient structure to avoid the application of section 112, ¶ 6. *See, e.g.*, *Lighting World*, 382 F.3d at 1359-63 (finding that the claim language "a connector assembly for connecting each pair of adjacent support members, said connector assembly being pivotally connected to said pair of adjacent support members" provided sufficient structure to avoid application of section 112, ¶ 6); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1023 (Fed. Cir. 2006) (finding that "a compression member for exerting a force onto said head such that said head is pressed against the hollow spherically-shaped portion" recited sufficient structure because the claim language "demonstrates that the compression member must fit inside the cylindrical opening and be of sufficient size to exert a force on the screw head, which implies structure").[5]

Further, it is clear from the specification that the term "tensioning component" denotes a structure, rather than just a function. *See Lighting World*, 382 F.3d 1354, 1361 (Fed. Cir. 2004) (relying in part on the fact that the written description used the term "connector assembly" as the name for a structure, and did not use the term in a purely functional manner, to hold that the claim was not subject to § 112, ¶ 6); *DePuy Spine*, 469 F.3d at 1023 (explaining that the specification made "clear that the term 'compression member' refers to a particular cylindrical insert and is not simply a general reference to any structure that will perform a particular

[5] Additional structure for the "tensioning component" is recited in other dependent claims. *See, e.g.*, '929 Patent, claim 4 ("The prosthetic heart valve system of claim 3, wherein the tensioning component includes a tubular body slidably connected to the line . . . ."); *id.*, claim 8 ("wherein the tensioning component includes a rotatable spool including a post").

function"). Throughout the '929 Patent, the phrase "tensioning component" is used to denote structure. *See, e.g.*, '929 Patent col. 3 ll. 49-53 (stating that the connector assembly includes "a tensioning component" and that the line that interconnects and passes through the stent posts is connected to the tensioning component). Moreover, each figure depicts the "tensioning component" as a definite structure—as an identifiable part of the connector assembly. Notably, in relation to some embodiments, the '929 Patent repeatedly uses the phrases "housing" and "tensioning component" synonymously. *See, e.g.*, *id.* col. 6 ll. 13 ("housing or tensioning component 60"); *id.* col. 11 ll. 48 ("housing or tensioning component 126"). The word "housing" has a structural meaning, i.e., "something that covers or protects: as **a:** a case or enclosure (as for a mechanical part or an instrument) **b:** a casing (as an enclosed bearing) in which a shaft revolves **c:** a support (as a frame) for mechanical parts." Merriam-Webster's Collegiate Dictionary 562 (10th ed. 2001). It is not a generic term such as "mechanism," "means," element," or "device." *Cf. Mass. Inst. of Tech. & Elec. for Imaging, Inc. v. Abacus Software*, 462 F.3d 1344, 1354 (Fed. Cir. 2006) (noting that such generic terms "typically do not connote sufficiently definite structure").

This case is unlike *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206 (Fed. Cir. 1998), the case upon which Edwards relies, because "[i]n that case, no other claim terms attributed structural significance to the elements at issue, and there was no evidence that the term at issue had an understood structural meaning in the art." *DePuy Spine*, 469 F.3d at 1024; *see also Lighting World*, 382 F.3d at 1362 (describing *Mas-Hamilton* as an "exceptional case" and stating that "we have seldom held that a limitation not using the term 'means' must be considered to be in means-plus-function form"). Here, the claim language itself provides structure, and the

specification makes clear that a "tensioning component" is some definite structure, rather than just any structure that will create tension.

Having found that "tensioning component" is not subject to section 112, ¶ 6, the Court next considers whether any construction of this claim term is necessary. Edwards argues that there must be no preexisting tension in the line in order for the tensioning component to "create" tension. Edwards focuses on the figures in the '929 Patent, which depict some slack in the line when the device is in the untensioned state. But the fact that the figures depict slack does not mean that there must always be slack prior to the creation of tension by the tensioning component. As previously explained, "[a] patent that describes only a single embodiment is not necessarily limited to that embodiment." *Saunders Grp.*, 492 F.3d at1332. "Even where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope . . . ." *Id*. Nothing in the claim language, specification, or file history precludes preexisting tension in the line, and there is certainly no demonstration of a clear intention to limit the claim scope to devices that create tension only in lines where there was no preexisting tension.

Edwards next points to a dictionary definition of "create," which defines "create" as "to cause to come into being." Hannah Decl. Ex. 24 at 472 (ECF No. 89-24). Edwards argues that to give effect to the word "create," the device must cause something to come into existence that previously did not exist—thus, according to Edwards, there must be no preexisting tension. The Court disagrees. It is true that the tensioning component must "create" tension—that is, it must create *new* tension, where said newly created tension did not previously exist. And the newly created tension must be sufficient "to inwardly deflect at least one of the stent posts." '929 Patent, claim 1. But the fact that the tensioning component must bring about new tension says

nothing about what tension, if any, already existed in the line. For example, there may be some preexisting tension on the line if the surgeon sutures the line tightly so that there is no slack in the line, but not tightly enough to produce sufficient tension to inwardly deflect the stent posts. In that scenario, the tensioning component may still create sufficient new tension to cause the stent posts to inwardly deflect. The Court is not persuaded that in order for the tensioning component to "create" tension within the line, there must be no preexisting tension within the line. Also, as previously explained, Edwards' proposed inclusion of the word "bends" would not provide any assistance to a jury and Edwards' requirement that the deflection be of "a desired amount" would only add more ambiguity to the claim. The Court therefore rejects Edwards' proposed construction in its entirety.

This claim term is not construed as a means-plus-function claim term and it does not preclude the presence of preexisting tension within the line. As clearly recited in the claim itself, the tensioning component must be able to create tension within the line to inwardly deflect at least of the stent posts. No further construction of this claim term is required.

4. "Movably disposed relative to free ends of the stent posts" and "an end that is transitional relative to the free ends of the stent posts"

Edwards proposes that the Court construe the claim term "movably disposed relative to free ends of the stent posts" to mean "capable of moving to a different position in relation to the free ends of the stent posts." Edwards also proposes that the Court construe the claim term "an end that is transitional relative to the free ends of the stent posts" to mean "an end that is capable of being moved to a different position in relation to the free ends of the stent posts." Medtronic asserts that inclusion of the words "to a different position" would only create ambiguity where previously there was none, and that the claim terms require no construction. Edwards appears to believe that the word "relative" requires construction because a jury would be unable to

understand what it means for something to be capable of movement relative to some other object. The Court disagrees. There is nothing to suggest that a jury cannot understand the word "relative," and so no construction of these claim terms is necessary.

5. "Tubular body slidably connected to the line"

Claim 4 recites a tensioning component that "includes a tubular body slidably connected to the line." Edwards' revised construction for the claim term "tubular body slidably connected to the line" is "tubular body through which the line can move along the inside of the tube in continuous contact." The main dispute between the parties is Edwards' contention that the tubular body must be hollow, and that the line must pass through the tubular body.

Although the parties disagree about whether or not the "tubular body" must be hollow, they do not argue that construction of the word "tubular" is necessary.[6] Medtronic asserts that "tubular" simply means "tube-like," and has a definition broader than "tube" because it can encompass something that merely *resembles* a tube. Because there is no indication that the word "tubular" would be unclear to the jury, and because the word "tubular" is used in the '929 Patent in a way consistent with its plain and ordinary meaning, no construction of this word is required.

Edwards points to the figures in the '929 Patent, which each depict a line that passes through the tubular body. Edwards thus contends that for the line and tubular body to be "slidably connected," the line must move along the inside of the tube in continuous contact. First, the Court notes that there is nothing in the claims, specification, or file history that suggest that the line and tubular body must be in "continuous contact." Even if the line did pass through the tubular body, it is unclear why the two must be in continuous contact in order to be "slidably connected." This additional language is entirely unsupported by the intrinsic evidence.

[6] Edwards initially argued that "tubular" should be construed as "cylindrical, hollow tube," but has since abandoned that construction.

Second, the Court acknowledges that perhaps the most obvious way to slidably connect the line and the tubular body is for the line to pass through and move along the inside of the tubular body. But here, Edwards is again attempting to read limitations from the specification into the broader claim language. While the figures depicting preferred embodiments reveal a line passing through the tubular body, the Court has already explained that "we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Phillips*, 415 F.3d at 1323. "It is the claims that define the metes and bounds of the patentee's invention" and "[t]he claims, not specification embodiments, define the scope of patent protection." *Kara Tech. Inc. v. Stamps.com, Inc.*, 582 F.3d 1341, 1347-48 (Fed. Cir. 2009). "The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims." *Id.* at 1348. Here, the claims require that the tubular body be "slidably connected to the line." This language only requires that the tubular body be connected to the line in such a way that permits sliding between the tubular body and the line. There is no clear disavowal of this broader claim scope, nor is there any demonstration that the inventor intended to limit the invention to tubular bodies through which the line passed. The Court therefore rejects Edwards' proposed construction and concludes that no additional construction of the claim term is required as the claim language itself can be readily understood.

C. '395 Patent

The '395 Patent is titled "Valve Holder for Tricuspid Heart Valve." The patent initially issued as U.S. Patent No. 7,018,407 ('407 Patent) on March 28, 2006. On October 12, 2007, Medtronic filed a reissue application, seeking to broaden certain claims of the '407 Patent. Of relevance here, Medtronic amended claim 9 of the '407 Patent, which reissued as claim 9 of the

'395 Patent—the claim asserted by Medtronic in this litigation. The patent was reissued on May 24, 2011, with the broadening amendments. Claim 9 of the '395 Patent is directed toward a valve holder for use during implantation of a prosthetic heart valve. The claimed holder allows the surgeon to deflect the commissure posts of the valve, thus reducing the possibility of inadvertently looping a suture around a commissure post or snagging and damaging the valve tissue during implantation. Claim 9 recites:[7]

> 9. A valve holder comprising a centrally positioned cylindrical support element having one open end, a coaxial hub extending from the other end of said cylindrical support element and joined together by a radial flange;
> coaxial thread **[**collecting means**]** *holding surface* encircled by said cylindrical support element and rotatably secured thereto;
> at least three circumferentially spaced valve support legs extending radially from said cylindrical *support* element, each of said legs including thread guiding and attaching means at a distal end thereof; and
> thread passage means in said cylindrical element in registry with each of said valve support legs.

The parties request construction of the following claim terms: "joined together by a radial flange" and "coaxial thread holding surface."[8]

1. "Joined together by a radial flange"

Edwards proposes that the above claim term be construed as "fastened together by a raised or projected edge, rib, or rim for strength that spreads or branches out in all directions from a common center." Medtronic proposes that the term be construed as "to bring into contact by a radial flange."

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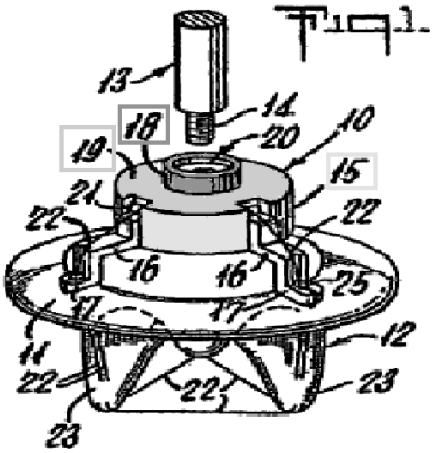
[7] "Matter enclosed in heavy brackets **[ ]** appears in the original patent but forms no part of th[e] reissue specification; matter printed in italics indicates the additions made by reissue." '395 Patent col. 1 ll. 5-9.

[8] The parties also initially requested construction of the claim terms "thread guiding and attaching means" and "thread passage means." They have since indicated, however, that there is no longer any disagreement regarding the function or structure for these claim terms and that the Court's assistance is no longer required.

The first issue is whether the word "radial" requires construction. Edwards suggests that radial means "branches out in all directions from a common center." Medtronic proposes no construction for "radial." The specification of the '395 Patent does not use the word "radial," but repeatedly refers to an "annular flange." *See, e.g.*, '395 Patent col. 3. ll. 25-29 ("Central support member 15 consists of a cylindrical structure having one open end facing stent 12 and terminating at the other end on coaxial hub 18 extending outward from annular flange 19."). Figure 1 of the '395 Patent is provided below:



The '395 Patent's Figure 1 (adapted).

The "radial" or "annular" flange is the structure denoted as 19 in the above figure. As the figure depicts, the "flange" branches out in a ring-like fashion, extending radially within a plane. Edwards' suggested construction of radial as "branches out in all directions from a common center" could introduce unnecessary confusion because it might inject a three-dimensional element into the minds of the jurors—they might believe that the flange must also branch upwards or downwards out of the plane, which it clearly need not do. To require such three-dimensional expansion would read out the preferred embodiments disclosed in the '395 Patent, a construction which is disfavored. *See Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1276 (Fed. Cir. 2008). Edwards' proposed construction for "radial" is therefore rejected. Further, there is no

indication that the word "radial," when given its plain and ordinary meaning, requires any additional construction.

Edwards also proposes a construction for the word "flange," based only on a dictionary definition, but provides no evidence or argument that a jury would be unable to understand the word "flange," or that the word has no commonly understood meaning in the art. Absent any indication that the word "flange" would be confusing to a jury, and given the fact that it is used in the '395 Patent in a manner consistent with its plain and ordinary meaning, the Court does not see the need to construe this claim term.

The primary dispute between the parties is the meaning of the words "joined together." Edwards suggests that the coaxial hub and cylindrical support element must be fasted together by the flange, whereas Medtronic argues that the two structures need only be brought into contact by the flange. Each party points to their own dictionary definitions of "join." Edwards provides the definition "to connect or bring together; to fasten; to couple; to combine"; Medtronic provides the definition "to be contiguous, close or in contact; to come together; to meet." Edwards' selection of one definition ("to fasten") among many possible definitions is curious, given that Edwards' own dictionary provides that "join" may also mean "to connect or bring together." A court should not rely on "a single dictionary definition to the exclusion of other dictionary definitions." *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1347 (Fed. Cir. 2009). "Join" has a plain and ordinary meaning that is broader than "fasten," and there is no clear disavowal in the patent or file history that suggests that a narrower construction

of "join" is appropriate.[9] The Court is not persuaded that a jury would be unable to understand the phrase "joined together," and so the Court declines to construe this claim term.

In sum, the Court concludes that the phrase "jointed together by a radial flange" should be given its plain and ordinary meaning, and the parties have failed to demonstrate that any construction by the Court would assist a jury in understanding this claim term.

2. "Coaxial thread holding surface"

Edwards proposes that the Court construe "coaxial thread holding surface" as "a surface having an axis in common with the cylindrical support element that, by rotating, grasps, retains, or collects threads or sutures." Medtronic asserts that this claim term requires no construction, and alternatively, proposes that the term be construed as "a holding surface sharing a common axis with the cylindrical support element."

The parties agree that for the "thread holding surface" to be "coaxial," it must have an axis in common with the cylindrical support element. This aspect of the claim term is undisputed and requires no assistance from the Court. The real dispute here is whether the surface must "collect" threads, rather than simply "hold" threads. Medtronic emphasizes the specification of the '395 Patent, which repeatedly refers to the thread being "collected" by the valve holder, and even refers to a "thread collection device." *See, e.g.*, '395 Patent col. 4 ll. 25-26, 32. In fact, the specification states that "[t]he key element of the present invention resides in the combination of the valve holder and the attaching threads which permit the threads to be collected by the valve holder . . . ." *Id.* col. 4 ll. 47-52. Edwards therefore contends that the

[9] Edwards argues that if the coaxial hub and cylindrical support member are not fastened together, then the valve holder would fall apart during use and the device would be inoperable. There is no evidence in the record, however, to support this argument.

specification supports only the "collection" of thread, and so "this concept must be reflected in the construction of this term." Edwards' Rebuttal Br. 48 (ECF No. 88).

The prosecution history, however, belies Edwards' argument. As evident from the reissued patent claim itself, the original patent (the '407 Patent) recited a "coaxial thread collecting means." The reissue application was filed in order to broaden this very language, and the claim that ultimately issued in the '395 Patent recites a "coaxial thread holding surface." In requesting the reissued patent, the applicant stated that "the scope of the issued claims may not be sufficient to cover the full scope of the inventive valve holder, as presented in the written description and the drawings. As such, the patented claims are defective in that they are narrower than the written description of the invention." Hannah Decl. Ex. 28, at 1 (ECF No. 89-28). Other statements made during prosecution of the '395 Patent confirm that the applicant intended to claim a device that held, and not merely collected, threads. *See, e.g.*, *id.* at 2 ("Claim 9 as amended clearly defines over the A-E publication at least because the A-E publication fails to disclose a thread holding surface rotatably mounted and centrally disposed with respect to said central support member and *adapted to hold threads*." (emphasis added)); *id.* at 4 ("As is clear from the patent disclosure, threads 22 are *retained or held* on groove 29 on the surface of axle 28." (emphasis added)).

Moreover, this issue was addressed during the prosecution of the amended claims. Claim 9 of the '395 Patent was initially rejected by the patent examiner, who believed the amended claim to be "an improper recapture of broadened claim subject matter surrendered in the application for the patent upon which the present reissue is based." U.S. Pat. App. No. 11/907,535, Examiner's Action (Non-Final Rejection), at 2 (mailed June 22, 2010). Citing portions of the original patent prosecution history, the examiner stated: "A broadening aspect is

present in the reissue and was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to claim subject matter that applicant previously surrendered during the prosecution of the application." *Id.* at 3. The examiner therefore found that "the narrow scope of the claims in the patent was not an error" and rejected the broader amended claims. *Id.* In response to the Non-Final Rejection, Medtronic argued that the amendments were not recapturing surrendered subject matter because claim 9 (filed in the original patent application as claim 12) was initially allowed without comment by the examiner. U.S. Pat. App. No. 11/907,535, Amendment and Remarks After Non-Final Rejection, at 12 (filed July 20, 2010). "Plainly, therefore, no surrender of subject matter occurred." *Id.* The examiner rejected Medtronic's arguments and issued a Final Rejection on September 16, 2010. Medtronic appealed the Final Rejection on November 16, 2010, and presented the same arguments as it had previously presented to the examiner. This time, however, Medtronic succeeded. "The arguments presented in the Appeal Brief of November 16, 2010, have been considered and *are persuasive*." U.S. Pat. App. No. 11/907,535, Examiner's Action (Final Office Action), at 2 (mailed Dec. 10, 2010) (emphasis added).[10]

Claim 9 of the reissued '395 patent plainly reveals that the phrase "collecting means" was replaced with "holding surface," and the prosecution history evinces a clear intent to broadly claim a "holding surface" rather than a "collecting means." Edwards, focusing on only the specification and extrinsic dictionary definitions of "hold" and "holding," basically asks the Court to overlook relevant prosecution history, and ignores Medtronic's successful prosecution of the broader claims as amended. In essence, Edwards wants the Court to act as if the '407

[10] The claims were again rejected as being based upon a defective reissue oath/declaration, but "[r]eceipt of an appropriate supplemental oath/declaration . . . will overcome this rejection." *Id.* Medtronic filed the supplemental declaration on March 3, 2011 and the notice of allowance of the reissued patent was issued on March 23, 2011.

Patent is the operative patent, and as if the claims were not amended and reissued in the '395 Patent. But in light of the intrinsic record, a "thread holding surface" is something broader than a surface that merely collects threads. The Court therefore rejects Edwards' proposed construction and concludes that "coaxial thread holding surface" should be given its plain and ordinary meaning. No construction is required.

D. '330 Patent

The '330 Patent, titled "Device or Apparatus for Manipulating Matter," is directed toward a device for manipulating matter in confined or inaccessible spaces in the body. For example, in one embodiment, the device is a surgical instrument that "enables the passage of a ligature around a bone, blood vessel, or other such body member, or the grasping of such a body member, without requiring the surgical instrument to be swept over a wide angle of motion." '330 Patent col. 5 ll. 14-18. In another embodiment, the surgical device is used to facilitate tissue collection. *Id.* col. 25 ll. 1-14. In yet another embodiment, the device includes a surgical screen that is expanded at or near a surgical site, which can be used to capture or block the passage of certain materials or to hold a tissue mass in a localized area. *Id.* col. 33 ll. 16-34.

Medtronic has asserted claims 1, 4, 7, 8, 10, 15, and 17-19 of the '330 Patent against Edwards. The parties have requested construction of the following claim terms: "pseudoelasticity/pseudoelastically/pseudoelastic," "alloy member bend(s) or twist(s) pseudoelastically in a lateral or helical sense to manipulate the matter on extending from the housing," "contain more martensite phase," "includes stress induced martensite," "distal segment assuming a first shape when extended from said bore and its alloy is in a substantially austenitic phase, and assuming a second shape when withdrawn into said bore and its alloy is stressed to contain more martensite phase," "means for moving," "means for expandably deploying," and

"handle means . . . for manually inserting said member through said cannula to distally extend said distal segment from said bore, and for withdrawing said distal segment into said bore."

1. "Pseudoelasticity/pseudoelastically/pseudoelastic"

Numerous claims of the '330 Patent contain language regarding pseudoelasticity. A brief background of the relevant science and prior art is helpful in understanding the meaning of these claim terms. During certain surgical procedures, it may be necessary to manipulate matter within a confined or inaccessible space, such as within a very deep wound or through a small incision or body aperture. '330 Patent col. 1. ll. 24-35. When introducing a surgical device into such a confined or inaccessible space, it may be desirable to compress the device in such a way that it can access the confined space, and then expand the device to its intended shape once it arrives at the surgical site. The device's ability to be compressed and then re-expanded often depends on the elastic properties of the materials used in that device. All materials are able to elastically, or reversibly, deform to some degree—meaning that if subjected to some external force or stress, the material can undergo a certain amount of strain and still be able to return back to its original form.[11] When materials are stressed beyond their elastic capabilities, they undergo what is known as plastic deformation, which is irreversible—i.e., the material will be unable to fully return back to its original form. Each material has a different elastic ability—for example, a rubber band can elastically deform to a much greater degree than a paper clip.

Prior art devices used "flexible steel wires which spring apart when extended from the distal end of a tube and which can be brought together again on withdrawal back into the tube." *Id.* col. 1 ll. 36-41. The materials used in those devices, however, could suffer from fatigue after repeated use or long storage. *Id.* col. 1 ll. 45-48. Other devices came into use that utilized shape

[11] Strain is the extent to which the material deforms in response to the stress, represented as a percent change in length of the material.

memory metals. Metals exhibiting a shape memory effect are able to "remember" their original shape, even after deformation. Shape memory metals, however, are often dependent on temperature change in order to accomplish their shape change. For example, they may need to be cooled while positioned in the body so that body heat thereafter actuates the shape memory effect. Alternatively, the metal may need to be heated above body temperature in order to actuate it after positioning. Use of these materials within the human body could cause damage to living tissues resulting from the dramatic temperature changes required. *Id.* col. 1 ll. 49-55.

Some shape memory metals, such as those employed in the '330 Patent, possess a property known as "pseudoelasticity," which allows for greater elastic deformation when subjected to stress. Through the use of pseudoelasticity, the metals can be deformed to a greater degree when subjected to an external stress (for example, when compressed to fit within a small cannula that can be inserted into a patient), yet still retain their ability to recover their original form when the stress is removed (e.g., when deployed from the cannula). "A pseudoelastic alloy is capable of being elastically deformed far beyond the elastic limits of conventional metals." '330 patent col. 1 ll. 20-22. Thus, like other shape memory metals, pseudoelastic metals can revert back to their original form even after deformation. Unlike other shape memory metals, however, they are not dependent upon temperature change. *See id.* col. 3 ll. 18-20 ("Under certain conditions, shape memory alloys exhibit pseudoelasticity, which does not rely on temperature change in order to accomplish shape change.").

There are two types of pseudoelasticity: linear pseudoelasticity and non-linear pseudoelasticity (also known as "superelasticity"). *See* '330 Patent col. 3 ll. 33-63. Non-linear pseudoelasticity, or superelasticity, involves a phase change between two different crystalline structures—these two crystal forms are known as "austenite" and "martensite." Within a certain

temperature range, metals possessing non-linear pseudoelastic properties are able to undergo a change from their stable austenitic phase to a martensitic phase when subjected to stress. This martensitic phase is also known as "stress-induced martensite." When the stress is removed, the metal is able to revert back to its austenitic phase, and thus recover its original shape. Thus, while in its austenitic phase, the metal is capable of exhibiting conventional elastic deformation, but then when stressed beyond a certain point, the metal begins to transform to its martensitic phase, allowing for even further elastic—or reversible—deformation. Superelasticity can be created through specific annealing processes, or through methods such as "solution treating and aging, or alloying." *Id.* col. 3 ll. 42-47. Linear pseudoelasticity, on the other hand, is not accompanied by a phase change between austenite and martensite. *See id.* col. 3 ll. 53-60. Rather, "[i]t is exhibited by shape memory alloys which have been cold worked or irradiated to stabilize the martensite, but have not been annealed in the manner discussed above." *Id.* A material exhibiting linear pseudoelasticity is capable of substantial reversible deformation, but not as much deformation as non-linear pseudoelastic materials. *See id.*

Edwards proposes that "pseudoelasticity/pseudoelastically/pseudoelastic" be construed as "elastically, isothermally deformed with an austenite to martensite phase transformation." Medtronic proposes that the term be construed as "(a material that is capable of) elastic deformation beyond the limits of conventional metals." First, with respect to Edwards' proposed insertion of the word "isothermally," Edwards appears to be arguing that pseudoelastic deformation does not rely on a temperature change—something with which Medtronic does not disagree. For a process to be isothermal, however, the temperature of the entire system must remain constant. The parties here agree that when a metal undergoes a phase transformation between austenite and martensite, there is some inherent heat transfer that occurs, resulting in

some temperature change associated with the transformation. Thus, the process is *not* "isothermal," and insertion of this word is inaccurate. In Edwards' Rebuttal Brief, Edwards clarifies its position, stating that while there may be some inherent temperature change that occurs during the phase transformation, the transformation does not involve any outside heating or cooling. It therefore revised its proposed construction, arguing that "pseudoelastically" means "elastically deformed with an austenite to martensite phase transformation without the application of external heating or cooling." Edwards' Rebuttal Br. 57 (ECF No. 88). This revision, while improved, is still somewhat inaccurate. When the device is placed within the human body during the surgical procedure, there may in fact be an *application* of external heating or cooling—for example, the temperature of the human body itself may operate so as to apply external heat to the device. The specification of the '330 Patent states that pseudoelasticity "does not *rely* on temperature change in order to accomplish shape change." '330 Patent col. 3 ll. 19-20 (emphasis added). The parties do dispute that pseudoelasticity does not rely on temperature change, and so language to this effect is appropriate and accurate. Regardless of whether or not external heat or cooling is applied, the pseudoelastic properties of the metal do not rely on any such external application in order to accomplish shape change.

The real heart of this dispute lies in whether or not pseudoelasticity requires an austenite to martensite phase transformation, as Edwards proposes. As discussed above, there are two types of pseudoelasticity, and only one of those types (non-linear pseudoelasticity, or "superelasticity") involves a phase transformation from austenite to martensite. The patent specification could not be more clear on this point, and the various references incorporated into the specification also provide such an explanation of pseudoelasticity. *See id.* col. 3 ll. 33-60. Edwards basically asserts that "pseudoelasticity" actually means "superelasticity," a construction

utterly unsupported by the specification. Moreover, the specification repeatedly explains that either type of pseudoelastic material can be used in the disclosed invention, but that superelastic materials are preferred. *See id.* col. 2 ll. 56-59; *id.* col. 2 l. 67-col. 3 l. 2; *id.* col. 3 l. 33-col. 4 l. 3; *id.* col. 4 ll. 43-46; *id.* col. 5 ll. 19-22. It is evident that superelasticity is *not* the same as pseudoelasticity, but rather, is a preferred *type* of pseudoelasticity.

Edwards relies in part on the following language found in the '330 specification:

> "Although pseudoelasticity is exhibited in both linear and non-linear variations, the present invention deals preferably with superelasticity, and further references to materials having the property will simply be designated as being 'pseudoelastic' or having shape memory. It will be understood, however, that the present invention may employ any appropriate elastic material, preferably shape memory alloy, whether linearly or non-linearly pseudoelastic."

'330 Patent, col. 16, ll. 9-17. Edwards asserts that this passage indicates that the inventor defined "pseudoelastic" to mean "superelastic." The fact that materials having superelastic properties are referred to in the patent as pseudoelastic does *not* mean that all references to pseudoelasticity require superelasticity. This passage merely says that while superelasticity is preferred, any pseudoelastic material will suffice, and so the patent will not distinguish between the broader category of pseudoelastic materials and the narrower, preferred category of superelastic materials. By way of analogy, the Court reads this passage as the inventor's statement that while squares are preferred to rectangles, all rectangles are permissible, and so the inventor will simply call squares "rectangles." Edwards mistakenly interprets this passage as saying that if the inventor is calling a square a "rectangle," then all references to rectangles must mean squares. But not all rectangles are squares, and this language in the specification does not suggest that they are.

Further, there are some claims in the '330 Patent which specifically require an austenite to martensite phase change. *See, e.g.*, '330 Patent, claim 4. If "pseudoelastic" already required

such a phase change, then this language would be superfluous in claim 4, which uses both the word "pseudoelastic" and also refers to an austenite to martensite phase change. The Court aims to construe claims to give effect to each word in the claim, and should not construe claim terms so as to render other language in the claim superfluous. *See Digital-Vending Servs. Int'l, LLC v. Univ. of Phoenix, Inc.*, 671 F.3d 1270, 1275 (Fed. Cir. 2012) (stating that a construction which renders claim language superfluous "is contrary to the well-established rule that 'claims are interpreted with an eye toward giving effect to all terms in the claim'" (citation omitted)). Thus, "pseudoelastic" must not already include an austenite to martensite phase change.

Edwards contends that various statements in the file history signify that the inventor only intended to claim an invention utilizing superelasticity. During prosecution of the '330 patent, it appears as though the examiner initially rejected some of the patent claims because a person skilled in the art would have found it obvious to substitute a pseudoelastic material, disclosed in a piece of prior art, into a different prior art device in order to provide a stronger, more elastic device. In response to the rejection, Medtronic argued that the invention of the '330 Patent was "not about a mere substitution of one material for another but rather that the invention requires that the device have a construction which utilizes the pseudoelasticity of the material during its operation." Hannah Decl. Ex. 30, at 5 (ECF No. 89-30) (emphasis in original). In contrast, the prior art device was not designed to utilize pseudoelasticity, but rather was constructed such that the ordinary elastic properties of a metal spring would suffice. *Id.* at 6. Medtronic emphasized that the '330 invention required a high degree of elasticity, and argued that the prior art references were "not properly combinable" and "even if combined, they do not contain the elements requisite to make the applicants' invention." *Id.* Medtronic also referred to a figure depicting superelasticity, emphasizing the high degree of elasticity involved in the materials used

in the '330 invention.[12] There is nothing in these statements which constitute a clear disclaimer or disavowal of linear pseudoelastic materials that do not involve an austenite to martensite phase change, especially in light of the clear specification language to the contrary.

The patent specification states that "[a] pseudoelastic alloy is capable of being elastically deformed far beyond the elastic limits of conventional metals." '330 Patent col. 3 ll. 20-22. The file history states that "[p]seudoelasticity is a special property of shape memory alloys" and that "[i]t is by definition a material state that is beyond the normal elastic range of a material." Hannah Decl. Ex. 30, at 5 (ECF No. 89-30). While pseudoelasticity does not rely on a temperature change, it does not necessarily require a phase transformation between austenite and martensite. Only "superelasticity," a preferred type of pseudoelasticity, involves such a phase transformation. The Court therefore construes "pseudoelasticity" as follows: "a property of a shape memory alloy in which its ability to elastically, or reversibly, deform does not rely on temperature change."

2. "Alloy member bend(s) or twist(s) pseudoelastically in a lateral or helical sense to manipulate the matter on extending from the housing," "contain more martensite phase," "includes stress induced martensite," and "distal segment assuming a first shape when extended from said bore and its alloy is in a substantially austenitic phase, and assuming a second shape when withdrawn into said bore and its alloy is stressed to contain more martensite phase"

Edwards requests construction of the above claim terms. Edwards' proposed constructions are provided in the table below:

[12] During prosecution, Medtronic quoted a portion of the Jervis patent, which is referred to in the '330 specification. That passage states that "[t]he reversible deformation associated with the formation and reversion of stress-induced martensite has been referred to as pseudoelasticity." *Id.* But as stated above with respect to a similar passage in the '330 specification, the fact that superelasticity is referred to as "pseudoelasticity" does *not* mean that all references to pseudoelasticity actually mean superelasticity.

Claim Term	Edwards' Proposed Construction
"alloy member bend(s) or twist(s) pseudoelastically in a lateral or helical sense to manipulate the matter on extending from the housing"	Alloy member pseudoelastically bends or twists laterally or helically springing spontaneously and fully open using a phase transformation from martensite, caused by 6% or greater strain, to austenite
"contain more martensite phase"	Pseudoelastic distal alloy segment, wire or basket sufficiently constrained, with 6% or greater strain, to cause an austenite to martensite phase change.
"includes stress induced martensite"	
"distal segment assuming a first shape when extended from said bore and its alloy is in a substantially austenitic phase, and assuming a second shape when withdrawn into said bore and its alloy is stressed to contain more martensite phase"	Distal alloy segment expands by pseudoelastically springing spontaneously and fully open into a first shape from a second shape using a phase transformation from martensite, caused by 6% or greater strain, to austenite

Edwards' proposed constructions for these claim terms share many similarities, the first of which is the inclusion of a 6% or greater strain limitation. Edwards indicated at oral argument, however, that it was no longer pursuing that particular limitation, and so the Court will not address it further. The next notable similarity between the various constructions is the language regarding a transformation, or phase change, between austenite and martensite. Claim 1 of the '330 Patent recites:

> 1. A device or apparatus for manipulating matter . . . comprising: (i) manipulator means at least partially constructed of at least one bent or twisted elongated shape memory alloy member having pseudoelasticity at the intended manipulation temperature, and (ii) a barrier material . . . ; (iii) a hollow housing or cannula . . . ., and (iv) actuating means for extending the at least one alloy member with said barrier member from the housing to manipulate matter within said space and for withdrawing the at least one alloy member into the housing, the arrangement being such that the at least one alloy member bend(s) or twist(s) pseudoelastically in a lateral or helical sense to manipulate the matter on extending from the housing at said manipulation temperature and the at least one alloy member becomes relatively straightened on withdrawal into the housing at said temperature.

This claim requires that the shape memory alloy member have pseudoelasticity, and that it "bend(s) or twist(s) pseudoelastically." Nowhere does this claim require an austenite to

martensite phase transformation. For the reasons previously discussed, "pseudoelasticity" does not necessarily involve a phase change, because there is also a form of pseudoelasticity—linear pseudoelasticity—which is not accompanied by a phase change. The Court rejected Edwards' proposed insertion of that unsupported limitation in the Court's construction of the term "pseudoelasticity" above, and it similarly refuses to insert the same limitation here. This claim language merely requires that a pseudoelastic material behave pseudoelastically.

Claim 4 recites that "said distal segment assuming a first shape when extended from said bore and its alloy is in a substantially austenitic phase, and assuming a second shape when withdrawn into said bore and its alloy is stressed to contain more martensite phase." This claim language already clearly requires that the alloy used in the distal segment undergo a transformation from being "substantially austenitic" to a form that, when stressed, "contain[s] more martensite phase." Edwards' proposed construction adds nothing to a jury's understanding of this claim.

Claims 10 and 19 recite the claim term "includes stress induced martensite." For example, claim 10 recites:

> 10. A surgical device comprising . . . a shape memory alloy wire . . . [and] means for moving the wire between a first position wherein the wire is constrained within the housing such that the wire includes stress induced martensite, and a second position wherein the wire is unconstrained by the housing and assumes an expanded memory shape . . .

Claim 19 recites: "A surgical device comprising . . . a basket comprising at least one member comprising a shape memory alloy . . . the basket being constrained within the sheath such that the shape memory member includes stress induced martensite . . . ." Again, it is clear from the claim language itself that when in a constrained configuration, the wire or basket includes stress induced martensite—i.e., martensite that is caused by the application of external stress. The

stress, in this context, is the stress applied by the constraining of the wire or basket within the housing or sheath. When that external stress is removed, such as when the wire or basket is moved into an unconstrained position outside of the housing or sheath, the alloy in the wire or basket will undergo some transformation back to its austenitic phase. The claims' use of the phrase "stress induced martensite," especially when read in light of the immediately surrounding claim language, indicates that the material must undergo some transformation from stress induced martensite to austenite. The Court perceives no need to adopt Edwards' construction, as the claim language is clear on its own.

Finally, with respect to Edwards' assertion that the alloy member or segment must "spring[] spontaneously and fully open," the Court finds no support for this argument in the intrinsic record. Edwards relies on two figures in the '330 specification, which depict a basket fully opening. Edwards states that "if the loop did not spring fully open, it is not clear how it could capture the target matter." Edwards' Rebuttal Br. 62 (ECF No. 88). There is no evidence that the invention would be inoperable if it only sprung partially open, and the Court can easily imagine situations in which the alloy segment would *not* spring fully open—for example, if the device were deployed in a very confined space close to a bone, where the immediate presence of the bone prevented the alloy segment from fully opening. It is unclear to the Court how a basket that was 99% open would fail to capture target matter. Edwards notes that during prosecution of the '330 Patent, Medtronic asserted that a high degree of elasticity was required in order to allow the metals to spring fully open. *See* Hannah Decl. Ex. 30, at 6 (ECF No. 89-30). These statements, however, merely explain the importance of pseudoelasticity to the invention—that it allows for the full opening of the metal without causing plastic deformation—thus distinguishing the invention from the prior art. These statements do not suggest that the '330 Patent claims read

only on devices that spring fully open. The ability to spring fully open may be desirable, but there is nothing in the intrinsic record to suggest that it is a required limitation of the patent's claims. Further, there is nothing in the intrinsic record, nor is there even attorney argument, to support insertion of the word "spontaneously." The Court therefore rejects Edwards' proposals.

Edwards' primary concern underlying its proposed construction of these claim terms, as well as of the claim terms addressed below, appears to be that the claims do not require that the device actually utilize the pseudoelastic properties of the metal(s) from which it is comprised. This concern, while earnestly felt and fervently urged, is not supported by the claim language—which explicitly requires that the pseudoelastic materials behave pseudoelastically. The Court finds that the claims themselves are sufficiently clear, and that Edwards' proposed constructions are either inaccurate or unhelpful. No construction of these claim terms is required.

3. "Means for moving"

Claims 8, 10, and 15 of the '330 Patent claims recite a "means for moving." Claim 8 recites:

> 8. A surgical device comprising: (a) a housing; (b) a barrier member . . . and (c) means for moving said barrier member between a first position wherein the barrier membrane and said loop are constrained within the housing, and a second position wherein the barrier membrane and said loop are is [sic] unconstrained by the housing such that said loop expands pseudoelastically when moved between the first position and the second position.

Claim 10 recites:

> 10. A surgical device comprising: (a) a housing; (b) a shape memory alloy wire having a barrier material disposed thereon; (c) means for moving the wire between a first position wherein the wire is constrained within the housing such that the wire includes stress induced martensite, and a second position wherein the wire is unconstrained by the housing and assumes an expanded memory shape; and (d) means for withdrawing the barrier member.

Claim 15 recites:

> 15. A remotely operated surgical device comprising: (a) an elongated housing; (b) a surgical screen comprising at least one member comprising a pseudoelastically deformable material; (c) means for moving the surgical screen between a first position wherein the surgical screen is constrained within the housing, and a second position wherein the surgical screen is deployed from the housing such that said pseudoelastically deformable member is constrained within the housing and expands pseudoelastically into an expanded shape when the surgical screen is moved between the first position and the second position.

The parties agree that the "means for moving" is recited in means-plus-function form. Medtronic argues that the function of the "means for moving" is recited in the claims themselves—for example, the function of the "means for moving" in claim 8 is moving a barrier member between a constrained first position within the housing and an unconstrained second position outside of the housing. Edwards, on the other hand, argues that the function of the "means for moving" is not only moving the barrier member, wire or surgical screen, but also pseudoelastically expanding the barrier member, wire or surgical screen. Edwards then identifies as corresponding structures the pseudoelastic portions of the device itself, such as the "pseudoelastically deformable loop."

As Medtronic correctly notes, the "means for moving" serves to move the pseudoelastic member from one position to another. By moving it from a constrained (or stressed) position to an unconstrained (or unstressed) position, it allows the pseudoelastic member to behave pseudoelastically—i.e., to undergo a shape change when no longer subjected to the stress of confinement within the housing. The "means for moving" does not itself have to be capable of pseudoelastic expansion—it must only make it possible for the pseudoelastic member to behave pseudoelastically, by moving the member from a constrained position to an unconstrained position. Thus, Edwards' proposed function is incorrect, as are the corresponding structures Edwards identifies. The function of the "means for moving" is the function clearly recited in

each of the claims. The corresponding structure that performs these functions is as Medtronic suggests—slider mechanisms, pistol grip or thumb actuated mechanisms, scissors handles, and syringe-plunger mechanisms. The Court therefore adopts Medtronic's proposed construction of the "means for moving" limitations.

4. "Means for expandably deploying"

Claim 19 recites:

> 19. A surgical device comprising a sheath; a basket comprising at least one member comprising a shape memory alloy, and a barrier material spanning said shape memory alloy, the basket being constrained within the sheath such that the shape memory member includes stress induced martensite; and means for expandably deploying said basket from said sheath.

The parties agree that the "means for expandably deploying" is a means-plus-function claim term, and that the function is "expandably deploying the basket from the sheath." As with the "means for moving" limitations, Edwards asserts that the "means for expandably deploying" must itself pseudoelastically expand, and thus points to corresponding structures that consist of pseudoelastic shape memory alloys. It is clear, however, from the claim language itself that the "means for expandably deploying" the basket does not itself have to pseudoelastically expand—it must only deploy the basket in such a way that permits the *basket* to pseudoelastically expand.

At oral argument, Edwards appeared to have conceded this point, arguing not that the deploying means itself had to be pseudoelastic, but instead emphasizing its concern that the claim must be read in a way that requires that *something* behave pseudoelastically to cause the expansion. The claim already requires that the basket include a shape memory alloy and that when constrained within a sheath, the shape memory alloy includes stress induced martensite. It is evident, therefore, that when the basket is deployed from the sheath, the basket's expansion

would be due, at least in part, to the removal of the stress and the reversion of the stress induced martensite to austenite—i.e., pseudoelastic behavior.

The Court adopts Medtronic's proposed construction of the "means for expandably deploying." The function is expandably deploying the basket from the sheath, and the corresponding structures are the slider mechanisms, pistol grip or thumb actuated mechanisms, scissors handles, and syringe-plunger mechanisms. The structure of the "means for expandably deploying" does *not* itself have to consist of a shape memory alloy with pseudoelasticity.

5. "Handle means . . . for manually inserting said member through said cannula to distally extend said distal segment from said bore, and for withdrawing said distal segment into said bore"

In each of their memoranda, the parties argued about whether or not this claim term, recited in claim 4 of the '330 Patent, is recited in means-plus-function form—Medtronic argued that section 112, ¶ 6 does not apply because the word "handle" itself recited sufficient structure, and Edwards asserted that section 112, ¶ 6 did in fact apply. At oral argument, however, there was very little discussion about this claim term, and Edwards did not rebut Medtronic's argument. In fact, Edwards explained that its position with respect to this claim term was the same as its position with respect to the "means for moving" and "means for expandably deploying" claim terms. Edwards' only concern was that the claim be read so as to require that the invention's pseudoelastic properties actually be taken advantage of—i.e., that something in the device must be required to actually behave pseudoelastically, rather than merely have the ability to behave pseudoelastically. As explained above, the claim language itself already requires an austenite to martensite phase transformation, and so Edwards' concerns that the claims may be read in a way so as to eliminate this requirement are unfounded.

Once the Court's understanding of the pseudoelasticity requirement was explained to the parties, Edwards seemed content with no further construction of this claim term. The Court therefore finds that while the words "means for" were used, the claim itself recites sufficient structure—i.e., a "handle"—to overcome the presumption that section 112, ¶ 6 applies. *See, e.g.*, *TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259-60 (Fed. Cir. 2008) (finding the presumption overcome); *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531-32 (Fed. Cir. 1996) (same). Given the nature of the parties' concerns, no additional construction of this claim term is required.

E. '630, '155 and '800 Patents

Edwards accuses Medtronic of infringing three related patents (the "McCarthy Patents"): the '630 Patent, the '155 Patent and the '800 Patent. These patents generally relate to annuloplasty, a surgical procedure used to repair the mitral and tricuspid valves in the heart. During annuloplasty, an artificial ring is sewn onto the natural annulus of the valve to provide support to the valve. The '630 and '155 Patents relate to the annuloplasty rings; the '800 Patent relates to the template used to deliver the annuloplasty ring to the surgical site. Edwards asserts claims 1, 10 and 11 of the '630 Patent, claims 1-4, 9, 11-14, 16, 19, 21-22 and 27 of the '155 Patent, and claims 1, 4-8, 10-12, 15-19, 21 and 22 of the '800 Patent.

The three McCarthy Patents are members of the same patent family. The '155 Patent is a continuation U.S. Patent No. 7,367,991 (not asserted in this litigation), which in turn is a continuation-in-part of the '630 Patent and U.S. Patent No. 6,908,482 (not asserted in this litigation). The '800 Patent is a divisional of the '482 Patent. The three patents share the same inventors, and the specifications of the patents are very similar—and at times, identical.

Some of the claim terms for which the parties have requested construction appear in two or more of the patents. The parties agree that the claim terms appearing in both the '630 Patent

and ’155 Patent should be construed together. Where the same claim term appears in the ’800 Patent, however, the parties disagree regarding the proper method of construction—Medtronic asserts that the terms in the ’800 Patent should be construed along with those in the ’630 Patent and ’155 Patent; Edwards contends that because the ’800 Patent is directed at the annuloplasty template, whereas the ’630 and ’155 Patents are directed at the annuloplasty ring, the claim terms appearing in the ’800 Patent should be construed separately. Despite Edwards’ fervent assertions, Edwards actually proposes nearly identical constructions for the same claim terms across the various patents. For example, with respect to the claim term “generally arranged about an axis,” Edwards’ proposed construction for this term in the ’630 and ’155 Patents is “generally arranged about the imaginary line through the center of the ring in the direction of the blood flow.” Edwards’ proposed construction for this same term appearing in the ’800 Patent is “generally arranged about the imaginary line through the center of the template in the direction of the blood flow.” Thus, with the exception of the substitution of the word “template” for “ring,” Edwards’ proposed construction is identical.[13] The Court therefore fails to understand why it should construe the same claim terms appearing in all three patents separately when even the party advocating such a position cannot demonstrate a meaningful reason to do so. The Court will therefore address the claim terms appearing in the three McCarthy Patents together.

1. “Generally arranged about an axis”

Medtronic argues that this phrase means “arranged about the line running perpendicular to, and through the center of, the reference plane within which a majority of the ring body lies.” Edwards contends that, with respect to the ’630 and ’155 Patents, the phrase means “generally arranged about the imaginary line through the center of the ring in the direction of the blood

[13] Further, for reasons to be discussed below, use of the word “ring” is actually appropriate for all three patents, and so Edwards’ one minor distinction is actually incorrect.

flow," and that with respect to the '800 Patent, the phrase means "generally arranged about the imaginary line through the center of the template in the direction of the blood flow." The parties do not appear to dispute the meaning of the phrase "generally arranged." Rather, they dispute the construction of the word "axis." Claim 1 of the '630 Patent recites:

> 1. An annuloplasty ring, comprising: a ring body generally arranged about an axis and being discontinuous so as to define two free ends, wherein the ring body has a relaxed configuration following a three-dimensional path such that the free ends are axially offset from each other a distance of between about 2-15 mm.

Claim 1 of the '155 Patent recites:

> A C-shaped annuloplasty ring sized and configured for attaching within a valve annulus, comprising: a relatively rigid inner body defining an elongated C-shaped path, the inner body generally arranged about an axis and being discontinuous so as to define two free ends with a break therebetween at the opening of the C-shaped path . . . .

Claim 1 of the '800 Patent recites:

> An annuloplasty ring template for holding a tricuspid annuloplasty ring during implantation against a tricuspid annulus, comprising: a body defined by a peripheral mounting ring generally arranged about an axis and being discontinuous so as to define two free ends . . . .

The Court first turns to the patents' specifications for insight as to the meaning of the word "axis" as used in these patent claims. The specification of the '630 Patent states:

> The term "axis," in reference to the illustrated ring, and other non-circular or non-planar rings, refers the line through the ring that passes through the area moment of inertia of the ring when viewed in plan view. This "axis" can also be viewed as imaginary line of blood flow within the valve orifice and thus within the ring when implanted therein.

'600 Patent col. 4 ll. 23-29. The specifications of the '155 and '800 Patents state:

> The term "axis," in reference to the illustrated ring, and other non-circular or non-planar rings, refers the line through the ring that passes through the area centroid of the ring when viewed in plan view. This "axis" can also be viewed as imaginary line of blood flow within the valve orifice and thus within the ring when implanted therein.

'155 Patent col. 4 ll. 35-41; '800 Patent col. 4 ll. 54-60. Both of these specifications further state that "[a]gain, the axis 44 in FIG. 2 lies at the centroid of the ring or along of the axis of blood flow through the ring 40 when implanted." '155 Patent col. 5 ll. 1-3; '800 Patent col. 5 ll. 24-26. The '800 Patent's specification confirms that the "axis" for the template is the same as the "axis" for the annuloplasty ring: "In this regard, the template 90 includes a peripheral mounting ring 94 generally arranged about an axis coincident with the axis 44 of the ring 40." '800 Patent col. 7 ll. 7-10; *see also* '155 Patent col. 6 ll. 49-52 (same). Thus, the "axis" for the annuloplasty ring and the "axis" for the template are the same axis, however that axis is determined.

The Court first notes that both Medtronic and Edwards suggest that the axis is a line running through the "center" of something. The patent specifications, however, state that the axis passes through the centroid of the ring. The *center* of the ring is not necessarily the same as the *centroid* of the ring—and the centroid has a definite, calculable position. *Compare* Merriam-Webster's Collegiate Dictionary 186 (10th ed. 2001) (defining "centroid"), *with id.* at 185 (defining "center"). While neither party notes this distinction, the Court cannot accept a construction that is inaccurate and at odds with the specification. Here, the inventor acted as his own lexicographer, defining the location of the axis, and the Court will not stray from the inventor's definition without any explanation as to why "centroid" is either incorrect or too difficult to understand.

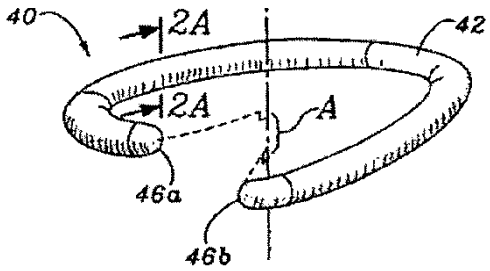
Medtronic also contends that the claim term requires that the axis run "perpendicular to, and through the center of, the reference plane within which a majority of the ring body lies." Thus, Medtronic asserts that for each of the claims in which the phrase "generally arranged about an axis" appears, a majority of the ring body must lie within a particular plane. This assertion is unsupported by the claim language, and becomes even less convincing when the various claims

within the patents are compared to each other. Claim 1 of the '155 Patent, for example, requires that the ring body be "generally arranged about an axis," and *also* requires that a "majority of [the inner body of the ring] lies within a reference plane." Claim 4, on the other hand, only requires that the ring body be "generally arranged about an axis"—it does *not* include language requiring that a majority of the ring body lie within a particular plane. Under Medtronic's proposed construction, both claim 1 and claim 4 would contain a limitation requiring that a majority of the ring lie within a plane, despite the fact that there is a clear difference between the language of these two claims. Medtronic's construction, therefore, ignores the differences between the different claims and renders the additional language in claim 1 superfluous—a construction that is disfavored. *See Digital-Vending Servs. Int'l*, 671 F.3d at 1275.

Further, the patent specifications explain that the invention "provides a *non-planar* or *three-dimensional (3D)* annuloplasty ring that is shaped to conform to a 3D annulus." '630 Patent col. 4 ll. 6-8 (emphasis added); '155 Patent col. 4 ll. 19-21 (emphasis added); '800 Patent col. 4 ll. 38-40 (emphasis added). "In the context of the present invention, a non-planar or three-dimensional annuloplasty ring has a nominal cross-sectional centerline that assumes a three-dimensional shape, or in other words does not lie in a single plane." '155 Patent col. 4 ll. 28-32; '800 Patent col. 4 ll. 47-51. The specifications also discuss the disadvantages of planar rings. *See, e.g.*, '155 Patent col. 4 ll. 48-55. This evidence further undercuts Medtronic's argument that for all of the patent claims, a majority of the ring body must lie within a single plane. Rather, where such a limitation is required, the claims themselves clearly provide it.

Medtronic argues that "every illustration of the axis in the specification depicts a line perpendicular to the main reference plane of the annuloplasty ring." Medtronic's Rebuttal Br. 14 (ECF No. 86). Medtronic then points to Figure 2, which is included in all three McCarthy

Patents. Medtronic contends that this figure shows the axis as "generally perpendicular to the plane of the ring." *Id.*



The '155 Patent's Figure 2.

This figure, however, does not illustrate any "reference plane." It is a stretch to conclude that this figure is depicting an axis perpendicular to the main reference plane of the annuloplasty ring when the figure does not purport to depict any such plane, nor does it demonstrate the angular relationship between that non-illustrated plane and the axis. Edwards then points to Figure 7C, which does depict a more planar ring. But that figure, too, does not purport to depict a "reference plane." In fact, the *only* figure which depicts the "reference plane" is Figure 8D. When viewing figures 8A and 8D together, one can see that this embodiment's "axis" is perpendicular to the reference plane. But the Court will not limit the claims to a preferred embodiment. This is not even a case where the patent describes only a single embodiment—other embodiments of the claimed invention do *not* include a reference plane within which a majority of the ring body lies. There is no indication that the inventor intended to limit the claim scope to only mostly planar rings.[14] In light of the claim language itself, the specification

[14] Medtronic cites language from the prosecution history in which the inventor described a prior art ring as not lying in any one plane. *See* Specht Aff. Ex. 2, at Edwards0003579 (ECF No. 87-2). The inventor did so to distinguish the prior art from Claim 1 of the '155 Patent, which explicitly requires that a majority of the ring lie within a reference plane. It is not disputed that Claim 1 contains this express limitation in the claim language itself. The cited prosecution history discussion is irrelevant to a construction of "generally arranged about an axis." The Court therefore finds Medtronic's argument unpersuasive.

language discussing the benefits of non-planar rings, and figures within the specification depicting non-planar rings (or failing to illustrate any reference plane), it is inappropriate for the Court to insert a limitation which is plainly absent, without any evidence that the inventor so intended.

Another defect in Medtronic's construction is Medtronic's to define the axis in relation to the reference plane—i.e., one must first determine the relevant reference plane, and then determine the axis that is perpendicular to it. Medtronic's procedure is backwards—the axis is not defined with respect to the reference plane, but instead, the reference plane is defined in relation to the axis. The axis is a line that passes through the centroid of the ring, in the direction of blood flow within the valve orifice. The reference plane is "defined as the plane that is perpendicular to the axis 152 at the elevation of the tricuspid annulus." '155 Patent col. 8 ll. 19-21. Thus, the axis is to be determined first, and once the axis is established, it is *then* possible to determine the reference plane—not vice versa.

Medtronic's primary argument appears to be that if the axis is defined only as an imaginary line running through the center of the ring in the direction of blood flow, then there could be multiple axes because the direction of blood flow may vary between individual patients. Medtronic asserts that even a variation by a few degrees could have a significant impact on whether or not the ends of the ring are "axially offset," as required by the claims. This may very well be a true statement. With no evidence to support it however, the Court is hard-pressed to make any conclusions about the direction of blood flow through heart valve orifices based solely on attorney argument. Medtronic's argument regarding the possibility of multiple axes is better suited for a validity challenge—not claim construction. And perhaps, with the supplementation of attorney argument by actual evidence, Medtronic's argument may eventually be persuasive.

The Court therefore rejects Medtronic's proposed construction in toto. Turning now to Edwards' proposed construction, Edwards argues that the axis recited in the '630 and '155 Patent claims runs through the center of the "ring," whereas the axis recited in the '800 Patent claims runs through the center of the "template." But the '800 Patent itself defines the "axis" as "the line through the *ring* that passes through the area centroid of the ring when viewed in plan view." '800 Patent col. 4 ll. 54-60 (emphasis added). This "axis" is "in reference to the illustrated ring, and other non-circular or non-planar rings." *Id.* The template in the '800 Patent also contains a "ring"—the "peripheral mounting ring." It is this ring that is "generally arranged about an axis." Thus, there is nothing to suggest that use of the word "ring" in construing this claim term in the '800 Patent is incorrect. The "axis" does not run through the center, or centroid, of the "template," as Edwards suggests. Rather, it runs through the centroid of the ring, as clearly explained by the '800 Patent's specification.

The Court therefore construes "generally arranged about an axis" as follows: "generally arranged about an axis, the axis being an imaginary line that passes through the area centroid of the ring, in the direction of blood flow." This construction provides both a fixed point through which the axis runs, as well as a direction in which that axis runs.

2. "Being discontinuous so as to define two free ends"

This claim term also appears in all three McCarthy Patents. As recited above, claim 1 of the '630 Patent provides that the annuloplasty ring have "a ring body generally arranged about an axis and being discontinuous so as to define two free ends," where the free ends are axially offset from each other. Claim 1 of the '155 Patent provides that the C-shaped annuloplasty ring have "a relatively rigid inner body defining an elongated C-shaped path, the inner body generally arranged about an axis and being discontinuous so as to define two free ends with a break

therebetween at the opening of the C-shaped path." Claim 1 of the '800 Patent recites an annuloplasty ring template having "a body defined by a peripheral mounting ring generally arranged about an axis and being discontinuous so as to define two free ends." Medtronic contends that this claim term should be construed as "the two free ends are more flexible than the body of the ring and both ends point in the downward (or outflow) direction." Edwards opposes this construction, asserting that the claim term requires no construction—it simply means that the ring body has a break or gap so as to create two free ends with no ring body therebetween.

The '155 Patent's claims explicitly provide that the ring is "c-shaped" or "split." *See* '155 Patent, claims 1, 11, 21. Many of the claims in that patent also explicitly provide that there be no ring body in between the free ends. *See* '155 Patent, claim 1 ("with a break therebetween at the opening of the C-shaped path"); *id.*, claim 11 ("with a break therebetween and no inner body therebetween"); *id.*, claim 21 ("with a break therebetween at the opening of the C-shaped path"). The shape of the peripheral mounting ring of the annuloplasty template mimics the shape of the ring. *See* '800 Patent, abstract ("A deliver [sic] template having a mounting ring with about the same shape as the ring . . . ."); *id.* col. 7 ll. 13-15 ("Desirably, the three-dimensional path of the peripheral mounting ring 94 is the same as that of the annuloplasty ring 40."). The patent specifications provide even more clarity as to what is meant by a "discontinuous" ring. Every figure in each of the three patents that depicts the "discontinuous" ring having "two free ends" reveals that there is no ring body present in the area between the two free ends. Further, all three patent specifications discuss the importance of having a discontinuous ring that does not interfere with the atrioventricular node ("AV node"), an important part of the electrical control system of the heart. Each patent describes the placement of the free ends of the ring on either side of the AV node to minimize the risk of damaging "the sensitive conduction system." '630

Patent col. 6 ll. 7-9; '155 Patent col. 6 ll. 18-42; '800 Patent col. 6 ll. 64-67. Moreover, in response to the patent examiner's rejection of some of the claims in the '155 Patent during prosecution, Edwards emphasized the "break in continuity" in the ring body, which it stated is "important so that when the ring is structured into the tricuspid annulus no sutures will pass through the important conduction system at the AV node." Chung Decl. Ex. 6, at 9 (ECF No. 82); *see also id.* Ex. 5, at 11-12. The Court therefore finds it clear what is meant by the claim term "discontinuous," and finds that no construction of this word is necessary.

Medtronic asserts that the "two free ends" must be more flexible than the rest of the ring body, and that both free ends must point in the downward direction. There is nothing in the claim language itself to indicate the relative flexibility of the two free ends with respect to the remainder of the ring body. There is also nothing in any of the patent specifications to suggest that such a limitation should be imported into the claims. In one preferred embodiment, the free ends are constructed to be more flexible than the rest of the ring body. *See* '155 Patent col. 8 ll. 38-58 (describing an embodiment in which the cross-sectional shape of the structural support is designed to provide more flexibility at the free ends). But the specifications repeatedly provide that the *entire* ring is flexible, referring on numerous occasions to the "elastic" or "pliable" material used to create the ring, and the ability to bend the ring to conform to an individual patient's annulus. *See, e.g.*, '630 Patent col. 2 ll. 43-54; *id.* col. 3 ll. 2-11; '155 Patent col. 2 ll. 52-62; *id.* col. 5 ll. 25-46; *id.* col. 6 ll. 29-33; '800 Patent col. 2 ll. 51-61. The fact that the ring is more flexible in one direction that another (i.e., that it is more flexible in bending up and down about the radial axes than about the central axis) does not provide any information regarding the relative flexibility of the free ends compared to the middle portions of the ring body. *See, e.g.*, '630 Patent, abstract ("The ring is more flexible in bending about radially extending axes than

about the central axis."); *id.* col. 2 l. 67-col. 3 l. 2; '155 Patent col. 3 ll. 8-10; *id.* col. 5 ll. 42-44 (explaining that the ring is formed in such a way that the free ends can be "more easily flexed up and down parallel to the axis than toward or away from one another"); '800 Patent col. 3 ll. 26-28. For example, the middle portion of the ring could be flexed in such a way that the free ends point up or down, without the free ends themselves being flexible at all.

Further, there are narrower dependent claims that expressly claim an annuloplasty ring with free ends that are "more flexible" than the annuloplasty ring body. *See* '155 Patent, claim 18 (reciting a ring "wherein the cross-section changes such that the inner body is more flexible in bending at the two free ends than in a midpoint thereof"); *id.*, claim 26 (same). If "free ends" were already construed to require this limitation, then these narrower dependent claims would be redundant. "[T]he presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim." *Phillips*, 415 F.3d at 1314. Medtronic's proposed construction is especially incorrect for the claims in the '800 Patent that describe a rigid template. The ends of the peripheral mounting ring of the template are *not* more flexible, in any embodiment of the invention.

The Court also finds Medtronic's reliance on the prosecution history unavailing. During prosecution of the '155 Patent, Edwards distinguished the invention from a prior art coil-shaped ring that included "free ends," but did not provide for a discontinuous ring with no ring body in the area between the free ends. The patent examiner rejected some of the claims, based in part upon the examiner's understanding of how the prior art coiled structure would be placed within the tricuspid annulus. Specht Aff. Ex. 2, at Edwards 0003592 (ECF No. 87-2). The patent examiner believed that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to have the free ends (thus break in continuity and support)

located at the anterior and septal sides since this is common sense as it is an area needing the least support . . . one would not want the break at the other side (posterior side) since the leaflet is the smallest in shape thus requires more support." *Id.* In response, Edwards argued that there was no reason to believe that the size of the leaflet should "determine[] the character of the adjacent ring structure." *Id.* at 0003581. Edwards stated that it was "not certain that the point where the ends of the coil structures terminate is any more flexible, at least in any significant way so as to affect the support of one or other leaflet." *Id.* This statement simply challenged the patent examiner's belief that the portion of the prior art coiled ring between the free ends would provide less support for the valve leaflet and thus would have obviously necessitated a particular orientation within the valve annulus. This statement says nothing about the structure of the '155 ring, nor does it constitute a disavowal of C-shaped or split rings in which the free ends are not more flexible than the rest of the ring body. Other statements made during prosecution of the '155 Patent referred to the narrower dependent claims, and did not disclaim the broader claim scope of the independent claims. *See id.*[15]

[15] Medtronic also relies upon statements made during prosecution of a later, unrelated patent (the '184 Patent). Assuming this is admissible extrinsic evidence, the Court is still not persuaded. The '184 Patent disclosed a ring with one free end that was stiffer than the other free end. The applicant distinguished the invention from the McCarthy Patents' rings, explaining that McCarthy disclosed a ring with two free ends of "apparently equal stiffness," and that it did "not disclose or suggest a ring body that is stiffer adjacent the first free end than adjacent the second free end." These statements do not suggest that the free ends of the McCarthy rings must be more flexible than the rest of the ring body. Other statements made during the prosecution of the '184 Patent related to whether the addition of a hinge point to an already flexible ring would have been obvious to a person having skill in the art. The applicant argued that the McCarthy rings already provided varying flexibility, noting that while the ring was relatively stiff around most of the ring, it was "more radially flexible at the free ends." Because the McCarthy rings, or at least an embodiment of those rings, already allowed for flexibility, a person having skill in the art would not have found the addition of a hinge-point to such a ring obvious or beneficial. In light of the fact that these statements are, at best, only extrinsic evidence, and in the context of the strong intrinsic evidence to the contrary, the Court does not view these statements as a clear disclaimer of the broad scope of the McCarthy Patents' claims.

There is also nothing in the claim language to support Medtronic's argument that both ends of the ring must point downward. The specifications of all three patents actually contradict such a narrowing limitation. The specification of the '630 Patent provides that because of the ring's flexibility, the free ends may be "more easily flexed *up and down* parallel to the axis than toward or away from one another." '630 Patent col. 5 ll. 5-10 (emphasis added). The'155 and '800 Patents' specifications expressly provide that the free ends need not be axially offset in the same direction from the reference plane, and that "one or both may even curve upward above the reference plane." '155 Patent col. 8 ll. 29-33; *see also* '800 Patent col. 8 ll. 54-58 ("Of course, the free ends 154*a*, 154*b* need not be axially offset from each other as is shown . . . [f]or instance, one or both of the free ends 154*a*, 154*b* may even curve upward above the reference plane 151."). Although preferred embodiment of the McCarthy ring does include two free ends that both point downward, *see* '155 Patent col. 8 ll. 38-41; *id.* figs.8A-8D; '800 Patent figs.8A-8D, it is improper for the Court to import such a limitation without a clear disclaimer or disavowal of the broader claim scope. Moreover, there are dependent claims in the McCarthy Patents which expressly recite an annuloplasty ring with free ends offset in the same direction. '155 Patent, claims 5, 15. These dependent claims would be meaningless if the Court adopted Medtronic's construction.[16]

[16] During prosecution of the '184 Patent, Edwards sought to claim a ring in which both ends pointed upward. Edwards argued that the McCarthy Patents did not disclose rings in which both free ends pointed upward, and discussed one of the illustrated embodiments of the '155 Patent in which both of the free ends pointed downward. These statements, however, were made only in relation to one of the preferred embodiments disclosed in the McCarthy Patents, and do not constitute a disavowal of the broad claim scope of those patents' independent claims. If these statements constituted any kind of disavowal of claim scope, they only disclaim a ring in which both ends point upward—they do not require that the free ends of the McCarthy rings both point downward. Moreover, this weaker extrinsic evidence fails to overcome the strong intrinsic evidence that the free ends may point either up or down.

The Court therefore rejects Medtronic's proposal that the free ends be required to be more flexible than the rest of the ring body and that they both point in the downward direction. Having rejected this construction, the Court finds that no other construction is necessary.

3. "A three dimensional path such that the free ends are axially offset" and "axially offset"

Claim 1 of the '630 Patent claims an annuloplasty ring having a ring body "following a three-dimensional path such that the free ends are axially offset from each other a distance of between about 2-15 mm." Claim 1 of the '155 Patent claims a C-shaped ring having an inner body that "curves such that the two free ends are both axially offset from the reference plane and from each other when in a relaxed configuration."[17] Claim 1 of the '800 Patent claims an annuloplasty ring template having a peripheral mounting ring following a three-dimensional path such that the free ends are axially offset from each other." Medtronic argues that "a three dimensional path such that the free ends are axially offset" should be construed as "a majority of the ring lies in a single plane with only the free ends in a non-planar position." Edwards contends that the phrase means only that the positions of the free ends are spaced apart with respect to the central axis.

As explained above with respect to the claim term "generally arranged about an axis," it is improper for the Court to import a limitation that the majority of the ring must lie within a single plane. Claims 1 and 21 of the '155 Patent, for example, already explicitly require a majority of the inner body of the ring to "lie[] within a reference plane through a midpoint of the inner body." There is no need for the Court to repeat this limitation by importing it into a construction of "axially offset"—doing so would render this claim language superfluous. *Bicon,*

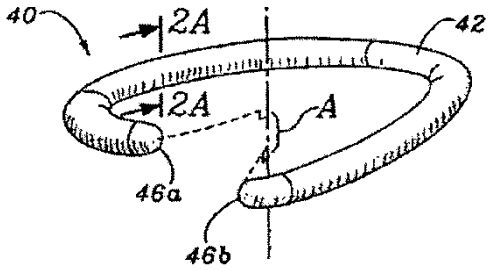
[17] Claims 11 and 14 of the '155 patent also contain the claim term "axially offset," but it is unnecessary here for the Court to recite every claim containing the disputed language.

Inc. v. Straumann Co., 441 F.3d 945, 950 (Fed. Cir. 2006) ("[C]laims are interpreted with an eye toward giving effect to all terms in the claim."). Claim 11 of the '155 Patent, on the other hand, does not contain the "reference plane" limitation, yet Medtronic urges the Court to impose it despite this conspicuous absence. Notably, claim 14, which depends from claim 11, *does* include a "reference plane" limitation—thus differentiating dependent claim 14 from independent claim 11. And as discussed above, the patent specifications describe the disadvantages of planar rings, *see, e.g.*, '155 Patent col. 4 ll. 48-55, and explain the non-planar or three-dimensional shape of the patents' annuloplasty ring, explicitly stating that the ring "does not lie in a single plane." *See, e.g.*, '630 Patent col. 4 ll. 6-8; '155 Patent col. 4 ll. 19-32; '800 Patent col. 4 ll. 38-51. Additionally, only Figures 8A-8D of the patents depict a ring in which the majority of the ring body lies within a reference plane. Thus, this is not a case where all of the figures in the patent depict only a single embodiment—rather, only one of many figures depict the construction that Medtronic urges. The Court therefore concludes that where the patents require that a majority of the ring lies in a single plane, such a limitation is already explicitly stated in the claims themselves, and the Court will not impose it elsewhere.

There is also nothing that supports Medtronic's argument that only the free ends of the ring may be in a non-planar position. In fact, in one of the embodiments of the invention, one of the free ends is, in fact, in a planar position. *See* '155 Patent col. 5 ll. 13-18 ("In this embodiment, the curvilinear anterior side 50*c* lies generally in a plane all the way to the free end 46*a*. Therefore, because the second free end 46*b* drops below the main part of the anterior side 50*c*, which generally defines an annulus reference plane for the ring and host annulus, then it is axially offset from the first free end 46*a*."). As previously discussed, the specifications describe how the ring is flexible such that the ends can be flexed up and down parallel to the axis. *See,*

e.g., *id.* col. 5 ll. 40-44; *id.* col. 6 ll. 29-33 ("[T]he oriented flexibility of the ring 40 facilitates the 3-D shape matching, between ring and tissue because the free ends 46*a*, 46*b* may be easily flexed with respect to one another along arcs that are generally parallel to the axis 44."). If the ring itself is as flexible as it is described to be in the specifications, then it is possible that portions other than the free ends may be non-planar. Further, the "ends" are simply the terminal points of the ring. For the "ends" to be axially offset, some portion of the ring adjacent to the ends would also have to be non-planar. Even in Figures 8A-8D, the only figures depicting a ring in which the majority of the ring body lies within a plane and the ends point downward from that plane, the portions of the ring immediately adjacent to the free ends are also non-planar. Medtronic does not explain how much of the adjacent ring structure could be non-planar and still conform to its requirement that only the "ends" be in a non-planar position. Thus, Medtronic's construction only introduces more uncertainty.

Finally, claim 14 of the '155 Patent, which depends from claim 11, requires the two free ends to be "axially offset from a reference plane." If claim 11, which provides that the ring body "is three-dimensional such that the two free ends are axially offset from each other," already required that the free ends be non-planar (thus offset from the plane), then the narrower dependent claim requiring that the free ends be offset from the plane would be utterly meaningless.



The '155 Patent's Figure 2.

Figure 2, included in each of the patent specifications and reproduced above, illustrates the "preferred axial offset" or an "exemplary axial offset" of the two free ends. "Radial lines are shown from each free end 46*a*, 46*b* to the central axis 44." '155 Patent col. 5 ll. 7-12. "The distance A between the intersections of these radial lines and the axis 44 represents the axial offset. The distance A may vary depending on the patient, but is typically between about 2.0 and 15.0 mm." *Id.* It is evident that the phrase "axially offset" has nothing to do with whether or not there is a reference plane within which a majority of the ring body lies, and does not dictate which portions of the ring may or may not lie within a particular plane. Rather, the axial offset pertains to the free ends' relative location along the central axis. Thus, consistent with the patent specifications and figures, the Court finds that "axially offset" means that a line drawn from one free end to the axis, with the line being perpendicular to the axis, will not intersect the axis at the same point at which a similar line drawn to the axis from the other free end intersects the axis. In other words, the free ends are offset as measured by the distance along the axis between the points where a perpendicular line drawn from each of the free ends to the axis intersects the axis.

4. "A relaxed configuration"

Claim 1 of the '630 Patent describes the three-dimensional path of the ring body when in a "relaxed configuration." Claims 1, 11 and 21 of the '155 Patent also claim a ring wherein the free ends of the ring body are axially offset when the ring is in a "relaxed configuration." Edwards asserts that "relaxed configuration" means "the configuration at rest prior to implantation." Medtronic contends that no construction of this claim term is necessary. Because the specification simply mimics the claim language and there is no guidance within the patent itself as to the meaning of this claim term, the Court finds that some construction of this claim term is warranted. During prosecution of the '155 Patent, the patent examiner noted that

"[a]lthough some prior art tricuspid annuloplasty bands disclose bands that conform to the tricuspid annulus, it is impossible to determine if these bands have offset ends . . . and further, if the offset is *present in a relaxed configuration prior to implant* (not just forced into an offset configuration by the annulus when placed in the body under stress)." Chung Decl. Ex. 7, at 2-3 (ECF No. 82) (emphasis added). In the Examiner-Initiated Interview Summary, the file states:

> [S]ince the claims, although having a relaxed configuration, no longer required a particular shape including offset ends to be present in the relaxed configuration, this opened the claims up to be potentially rejectable over an c-shaped or split planar ring that is capable of conforming to the offset non-planar tricuspid annulus (thus capable of having offset ends when implanted . . .) or if stressed or held in such a conformation outside the body. Thus the examiner suggested moving the "relaxed configuration" to an end portion of the claim such that it is clear that the ends are offset in a relaxed configuration and thus avoiding any possible interpretations as discussed above.

Id. at 1. Edwards also cites to dictionary definitions of "relaxed," defining the term as "being free of tension." The Court finds Edwards' arguments persuasive and concludes that "a relaxed configuration" means the configuration at rest, when not stressed, prior to implantation.

5. "A majority of which lies within a reference plane"

Medtronic argues that "a majority of which lies within a reference plane" means "a majority of the ring lies in a single plane with only the free ends in a non-planar position." Edwards contends that the words should be given their plain and ordinary meaning, and that no construction is required. This claim term appears in claims 1 and 21 of the '155 Patent. Claim 1 of the '155 Patent recites:

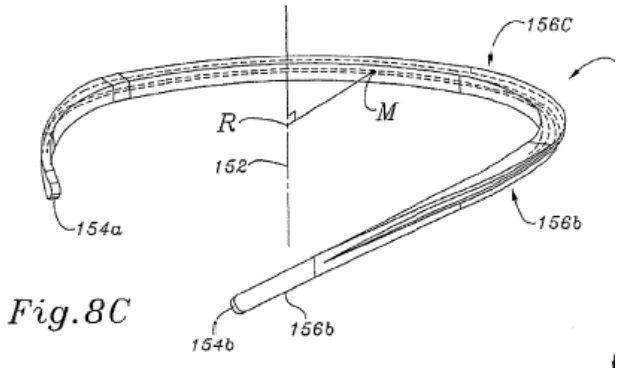
> A C-shaped annuloplasty ring . . . comprising: a relatively rigid inner body defining an elongated C-shaped path, the inner body generally arranged about an axis and being discontinuous so as to define two free ends with a break therebetween at the opening of the C-shaped path, wherein the inner body is sized to extend within and around the valve annulus and a majority of which lies within a reference plane through a midpoint of the inner body and wherein the inner body curves such that the two free ends are both axially offset from the reference plane and from each other when in a relaxed configuration . . .

Similarly, claim 21 of the '155 Patent recites a "C-shaped annuloplasty ring" having an inner body wherein "a majority of which lies within a reference plane through a midpoint of the inner body" and wherein "at least one of the two free ends is axially offset from the reference plane when in a relaxed configuration."

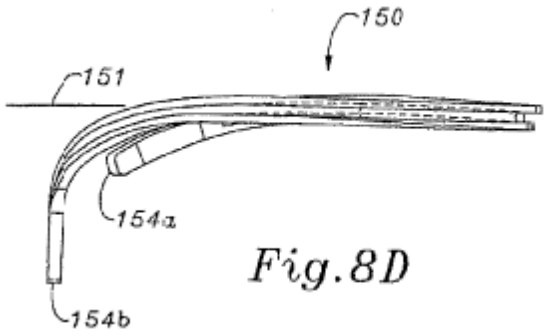
Medtronic contends that for a "majority" of the ring to lie in a plane, only the free ends may be non-planar. For support, Medtronic points to a description of a preferred embodiment in the '155 specification, in which a majority of the structural support of the ring is located in the annulus reference plane and the two free ends both curve away from the plane. *See* '155 Patent col. 8 ll. 14-17; *id.* figs.8A-8D. Figure 2 of the '155 Patent, however, describes a ring in which one of the free ends *is* within the same plane as the adjacent ring body. *See* '155 Patent col. 5 ll. 13-18 ("In this embodiment, the curvilinear anterior side 50*c* lies generally in a plane all the way to the free end 46*a*."). As discussed above, there is no support for the assertion that only the free ends may be non-planar. Rather, the entire ring is designed to be flexible. For a "majority" of the ring to be planar, more than fifty percent of the ring must lie within a plane—up to forty-nine percent of the ring may be non-planar and still conform to the requirement that a majority of the ring lie within a plane. There is nothing in the claims or specification that specifies which portions of the ring may comprise that forty-nine percent, or that limit that forty-nine percent to only the free ends. Further, as previously explained, the "ends" are only the terminal points of the ring, and for the "ends" to be non-planar, some portion of the ring body adjacent to the ends must also be non-planar. Medtronic's construction does not allow for this practical necessity.

Claims 1 and 21 provide that the reference plane be "through a midpoint of the inner body." *See also* '155 Patent col. 2 ll.40-43 ("The ring body has a relaxed configuration following a three-dimensional path such that the free ends are axially offset from an annulus

reference plane through a midpoint of the ring body."). Further, the specification is clear, and the parties do not dispute, that the reference plane is perpendicular to the axis. *See id.* col. 8 ll.14-19 (defining the annulus reference plane as perpendicular to the axis). Below are the figures from the '155 Patent that depict the reference plane:



The '155 Patent's Figure 8C



The '155 Patent's Figure 8D

The '155 Patent defines the annulus reference plane as follows:

> "The annulus reference plane 151 is defined as the plane that is perpendicular to the axis 152 at the elevation of the tricuspid annulus. That elevation, in turn, is represented in the drawings by the midpoint of the anterior side 156*c*, or at least the midpoint of the larger cross-section portion thereof (as detailed below). FIG. 8C illustrates a midpoint M in the anterior side 156*c* that represents the nominal elevation of the host annulus. A perpendicular line to the axis 152 intersects point R. The reference plane is thus perpendicular to the axis 152 through R."

Id. col. 8 ll. 18-28.

The Court concludes that for a "majority" of the inner body of the ring to lie "within a reference plane," portions other than only the free ends of the ring may lie in a non-planar position. As long as more than fifty percent of the body lies within a plane, this claim limitation is met. The reference plane is simply a plane that is perpendicular to the axis and that goes through a midpoint of the inner body.[18]

[18] The Court also notes that there may be several "midpoints" of the inner body. The "midpoint" is not depicted as the circumferential midpoint of the ring, but is rather the midpoint of a cross-section of some segment of the ring. *See* '155 Patent fig.8C. Thus, it appears as

6. "Peripheral mounting ring"

Both parties agree that the "peripheral mounting ring," as recited in claims 1, 10, 21 and 22 of the '800 Patent, is the outermost part of, or on the perimeter of, the template. The crux of the dispute regarding construction of the "peripheral mounting ring" is that both Medtronic and Edwards are concerned that the *other* party is trying to restrict this claim term to encompass only the "outwardly facing groove" disclosed as a preferred embodiment within the patent. *See* '800 Patent col. 7 ll.49-55 (describing the "radially outwardly opening channel or groove" that "retains the [annuloplasty] ring 40 in place around the template 90"). Both parties agree that such a construction is incorrect, and that the "peripheral mounting ring" is not synonymous with the "outwardly opening channel or groove." The Court agrees that this claim term should not be so restricted. There does not appear to be any other dispute regarding this claim term, and so no construction is necessary.[19]

7. "Annulus reference plane through a midpoint of the rigid body"

This claim term appears in claims 21 and 22 of the '800 Patent. Claim 21, for example, recites:

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though the "midpoint" can be anywhere along the ring, and there may be more than one reference plane in which a majority of the ring body lies. *See id.* col. 8 ll.24-26 (describing "*a* midpoint M," suggesting that there may be more than one midpoint" (emphasis added).

[19] To the extent that Medtronic does, in fact, contend that the "peripheral mounting ring" should be construed as a "circular band," the Court rejects such a construction. Even Medtronic agrees that the peripheral mounting ring need not be "perfectly circular," thus calling into question Medtronic's suggested insertion of the word "circular" to begin with. *See* Medtronic's Rebuttal Br. 50 (ECF No. 86). The patent specification states that the peripheral mounting ring is "about the same shape as the [annuloplasty] ring," which may be "non-circular." '800 Patent, abstract & col. 4 l. 55; *see also id.* col. 7 ll. 12-15 (describing the "three-dimensional path of the peripheral mounting ring" as "the same as that of the annuloplasty ring"); *id.* col. 7 ll. 45-48 (describing an exemplary embodiment in which the mounting ring extends only three-quarters around the axis). It is clear that the peripheral mounting ring, like the annuloplasty ring to which it is secured, need not be circular. The Court also fails to see how insertion of the word "band" would make the claim term any clearer to a jury.

> An annuloplasty ring template, comprising: a rigid body defined by a peripheral mounting ring generally arranged about an axis and being discontinuous so as to define two free ends, the mounting ring following a three-dimensional path such that the free ends are axially offset from an annulus reference plane through a midpoint of the rigid body, wherein the peripheral mounting ring extends about three-quarters circumferentially about the axis.

Medtronic asserts that the disputed claim term means "the plane that is perpendicular to the axis and contains a majority of the ring body." Edwards proposes that the claim term be construed as "a reference plane that passes through the center of the template and that is perpendicular to the axis." Both parties agree that the annulus reference plane is perpendicular to the axis.

Medtronic contends that the reference plane must contain a majority of the ring body. Unlike some of the claims in the '155 Patent, however, claims 21 and 22 of the '800 Patent do not expressly require that a majority of the rigid body of the template lie within a plane. Other claims within the '800 Patent, such as claims 9 and 20, do explicitly require that "the majority of the peripheral mounting ring lies within a plane." While claims 9 and 20 do not depend from independent claims 21 and 22, the fact that the inventor specifically required at times that a majority of the ring lie in a plane, and at other times did not include similar language, strongly suggests that importation of such a limitation into claims 21 and 22 would be improper. In the preferred embodiment of the peripheral mounting ring, as depicted in Figure 7C of the '800 Patent, "a majority of the mounting ring 112 lies in a plane." '800 Patent col. 8 ll. 8-12. There is no disavowal or disclaimer in the specification or prosecution history, however, that suggests that the Court limit the broad claim language to only the depicted preferred embodiment. Absent any such disclaimer, the inventor is entitled to the full scope of his claims.

Edwards argues that the claim language "through a midpoint of the rigid body" suggests that the plane passes through "the center of the template." This is not an accurate description of the reference plane. As explained above, the "midpoint" through which the plane passes is a

midpoint of a cross-section of the body. There may be numerous midpoints, depending on where the body is transected. The word "center," as proposed by Edwards, does not sufficiently convey this location. Further, the plane does not go through a midpoint of the "template," but rather goes through a midpoint of the "rigid body" of the peripheral mounting ring of the template.

The '800 specification describes the "annulus reference plane" of the annuloplasty ring. *See* '800 Patent col. 5 ll. 37-41 (describing the "main part of the anterior side 50*c*" as "generally defin[ing] an annulus reference plane for the ring and host annulus"). This annulus reference plane is "the plane that is perpendicular to the axis 152 at the elevation of the tricuspid annulus." *Id.* col. 8 ll.42-44. "That elevation, in turn, is represented in the drawings by the midpoint of the anterior side 156*c*, or at the least the midpoint of the larger cross-section portion thereof . . . ." *Id.* col. 8 ll. 44-46. There is no particular description, however, of the "annulus reference plane" of the template. The '800 specification states that it is desirable for the three-dimensional path of the peripheral mounting ring of the template to be the same as the path of the annuloplasty ring which is attached to the template. *See* '800 Patent col. 7 ll. 13-15. As previously explained, not all annuloplasty rings must be mostly planar. Thus, there does not appear to be any requirement that all peripheral mounting rings be mostly planar either.

Based on the claim language, the "annulus reference plane" appears to serve as a point against which to measure the axial offset of the free ends of the peripheral mounting ring of the template. But there is no requirement, in either the claims or the specification, that a majority of the peripheral mounting ring must within that reference plane (except where the claims themselves otherwise so require, as in claims 9 and 20). Nor has Medtronic pointed to anything in the prosecution history that would support such a limitation. The Court therefore construes

"annulus reference plane through a midpoint of the rigid body" as "a reference plane that passes through a cross-sectional midpoint of the rigid body and that is perpendicular to the axis."

III. CONCLUSION

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT the disputed claim terms and phrases are construed as set forth in this Order.

Dated: May 16, 2013

s/Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge